Food·Drug·Cosmetic Law

The editorial policy of the monthly FOOD DRUG COSMETIC LAW JOURNAL is to record the progress of this law and to provide a constructive discussion of it, according to the highest professional standards. The JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need.

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

About the Authors

A representative of the Food and Drug Administration—**F. Leslie Hart,** Chief of the Boston District—sums up the history of food adulteration before passage of the 1906 Act. He presents interesting sidelights on crime and punishment in the sophistication of foods since the time that commerce began.

The second article in the January issue of the JOURNAL, "An Objective Approach to the Problem of Developing Grades and Standards," presents the views of an author new to the pages of our magazine—**Amihud Kramer.** Dr. Kramer is a professor in the Department of Horticulture, College of Agriculture, University of Maryland.

A November, 1951 report of the Food Protection Committee of the National Research Council is brought to our readers this month. Concerning the use of chemical additives in foods, the statement was released in pamphlet form during December.

The council, formed almost forty years ago under a Congressional charter held by the National Academy of Sciences, provides an independent group of scientific counselors in cooperation with the government.

Dean **Charles B. Nutting** of the University of Pittsburgh School of Law has been a professor at that institution since 1946. In the same year he became vice dean, and has been dean since 1949. Prior to his present association with the university, he had served as associate solicitor in the United States Department of Agriculture (1943-1946).

Dean Nutting is a member of the American Law Institute, the American Judicature Society, the bar associations of Allegheny County and of Pennsylvania, and of the American Bar Association, where he is noted for his service with the Administrative Law Council.

It is indeed appropriate that an address by **Paul B. Dunbar,** delivered on November 14, 1951, on the occasion of his acceptance of an award of distinction by the Food Law Institute, Inc. be presented in this issue of the JOURNAL, together with a tribute to him by C. W. Crawford, United States Commissioner of Food and Drugs, presented at the time of the ceremony.

Dr. Dunbar, retired Commissioner of Food and Drugs, was cited by the institute for his notable public service in administering the national food and drug law. He is well known to JOURNAL readers.

Lester L. Lev describes the *Nutrilite* consent decree and notes the background of negotiations which led up to it. Mr. Lev is a member of the California bar.

Also in the January JOURNAL, **Edward E. Turkel** presents his commentary on administrative and judicial happenings in the field of food, drug and cosmetic law. A quarterly feature, "Significant Comments" summarizes developments since its last appearance in the October, 1951 issue.

Meeting of Food and Drug Men

Minutes of Third Annual Meeting of Division of Food, Drug and Cosmetic Law in Section of Corporation, Banking and Business Law of American Bar Association.—This meeting was held at the new Law Center of New York University in New York City, on September 19-20, 1951. It included three sessions. They were a morning discussion session on September 19, a morning discussion session on September 20, and a special luncheon session on that day. The Food Law Institute, Inc., was the host at the luncheon of the last session. It was in the nature of a ceremony to honor Dr. Paul B. Dunbar, retired United States Commissioner of Food and Drugs, for his long and great public service in administering the national food and drug law. The program included an introductory statement by the Chairman of the Division and tributes by Charles W. Crawford (United States Commissioner of Food and Drugs), T. E. Sullivan (President of Association of Food and Drug Officials of the United States), Ole Salthe (Executive Secretary of The Nutrition Foundation), William N. Strack (General Counsel for Swift & Co.), George H. Sibley (General Attorney for E. R. Squibb & Sons), and Hugo Mock (General Counsel for Toilet Goods Association). In behalf of the Division the Chairman presented a scroll award of distinction to Dr. Dunbar, who then made a response.

The program for the discussion sessions was as follows:

Morning Session on September 19: (*1*) Introductory remarks by Malcolm Fooshee, Chairman of the Section, and Charles Wesley Dunn, Chairman of the Division. (*2*) Address by Charles W. Crawford, United States Commissioner of Food and Drugs, and T. E. Sullivan, President of Association of Food and Drug Officials of the United States. (*3*) Round table discussion of "Imitation Jam" decision by United States Supreme Court under Federal Food, Drug, and Cosmetic Act, by H. Thomas Austern, General Counsel for National Canners Association, Charles Wesley Dunn, General Counsel for Grocery Manufacturers of America, Inc., and Robert W. Austin, Visiting Lecturer in Business Law at Harvard Graduate School of Business Administration. (*4*) Discussion of uniform state food, drug and cosmetic laws, by Carl R. Miller, Counsel for A. E. Staley Manufacturing Company. (*5*) Floor discussion of the foregoing addresses and papers.

Morning Session on September 20: (*1*) Round table discussion of proposed food chemical amendment to Federal Food, Drug, and Cosmetic Act, by Vincent A. Kleinfeld, Counsel for House Select Committee to Investigate the Use of Chemicals in Food Products, James M. Best, General Counsel for The Quaker Oats Company, and Kenneth E. Mulford, General Manager of Industrial Chemicals Department of Atlas Powder Company. (*2*) Round table discussion of international uniformity in the food, drug and cosmetic law, by William W. Goodrich, Principal Attorney of Food and Drug Division in Office of General Counsel for Federal Security Agency, Robert E. Curran, K. C., Legal Adviser to Canadian Department of National Health and Welfare, and Charles A. Adams, C. B. E., Director of Food Standards and Labelling Division in United Kingdom Ministry of Food. (*3*) Round table discussion of major drug law problems, by James F. Hoge, General Counsel for Proprietary Association of America, and Raymond O. Clutter, Attorney for Eli Lilly & Co. (*4*) Report on proposed Uniform Commercial Code, by Frank T. Dierson, Associate General Counsel for American Pharmaceutical Manufacturers' Association. (*5*) Floor discussion of the foregoing papers.

It is added: (*1*) The Committee on Food Standards submitted the report annexed hereto. The Chairman also read a report by the special committee of the

(Continued on page 80)

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Journal

A HISTORY OF THE

Adulteration of Food Before 1906

By F. LESLIE HART

The Author Discusses the History of Adulteration During Four Main Periods — Ancient Times, the Medieval Period, the Period of Development of Commerce and the Legislative Period up to 1906

"And chalk, and alum and plaster are sold to the poor for bread."—
Alfred, Lord Tennyson, *Maud* (1854).

THE ADULTERATION of foods is as old as commerce itself. In early times foods were few and simple. Trade existed for the most part through barter. Markets offering fully prepared foods had not yet come into existence. Rather, such markets as did exist offered raw and crude foodstuffs. Grains and spices were not ground; vegetables and fruits were fresh or dried. Only such foods as honey, ales and wines, and oils offered much chance for sophistication. Of course, crude cheating did occur. The ancient caravans crossing the Gobi Desert with bales of tea or musk sometimes added considerable weight to this valuable merchandise by inserting rocks, and even chunks of lead into the bales. As commerce developed and knowledge spread, adulteration grew more subtle. Spices were ground, flour was milled or baked into bread, milk and cheese became articles of commerce. Each offered more opportunity for hidden sophistication. A demand for laws to control this practice then arose.

For the purpose of this article, the word "adulteration" will have a restricted meaning. It will thus differ from the definition given in the Federal Food, Drug, and Cosmetic Act [1] in that natural happenings to foods, such as insect infestation, or rot, and accidental contamina-

[1] SRA FDC 1, Sec. 402.

Mr. Hart Is Chief of the Boston District, Food and Drug Administration, Federal Security Agency

tions with no thought of gain, will be excluded. The Encyclopedia Britannica uses a definition of "adulteration," carried through several editions, that is apt: "Adulteration is the act of debasing a commodity with the object of passing it as, or under the name of, a pure or genuine commodity for illegitimate profit, or the substitution of an inferior article for a superior one, to the detriment of the purchaser." This author would like to add "or criminally careless inclusion of poisonous ingredients in food."

Such a definition would exclude the incident narrated by Xenophon in *Anabasis* in which many of the Grecian soldiers were poisoned by eating a certain kind of honey. They first became intoxicated; then, if they continued to indulge, became delirious. This toxic effect is said to be due to a substance natural to the flowers of a species of rhododendron from which the bees sipped nectar. The definition would include the famous beer poisoning epidemic in Manchester, England (of which more later), since in this case the arsenic got into the beer through motives of profit. The addendum to the definition would include the very recent (August, 1951) food poisoning epidemic in Pont-St. Esprit, France, in which four died and some two hundred became seriously ill from eating rye bread made from flour contaminated with ergot. The baker admitted knowing the flour was contaminated. For this reason he did not sell that batch of bread in his home town but sent it to Pont-St. Esprit, some three hundred miles away.

The history of adulteration rather naturally falls into four periods:

(1) Ancient times.
(2) The medieval period, up to about 1500 A. D.
(3) The period of development of commerce, 1500 to about 1800.
(4) The legislative period, 1800 to date.

Ancient Times

The laws of Moses contain edicts that exactly parallel clauses found in most modern food laws:

> And the fat of the beast that dieth of itself, and the fat of that which is torn with beasts may be used in any other use, but ye shall in no wise eat of it. (Leviticus, 7:24.)
>
> Thou shalt not have in thy bags divers weights, a great and a small; thou shalt not have in thy house divers measures, a great and a small; but thou shalt have a perfect and just weight, a perfect and just measure shalt thou have. (Deuteronomy, 25:13-15.)

The late Dr. W. B. White [2] cites fragments from Chinese literature on adulterations practiced during the early dynasties. As early as the second century B. C., *The Institutes* of Chou said: "The Supervisor of Markets had agents whose duty it was to prohibit the making of spurious products, and the defrauding of purchasers." Eight hundred years later, during the T'ang Dynasty, the legal code provided:

> When dried or fresh meats cause men to become ill, all the left-over portions should be speedily burned. The violator will be flogged 90 strokes. He who deliberately gives or sells it to another will be banished for a year, and if the person to whom it has been given or sold dies, the offender will be hanged.

White also quotes an early Sanscrit law, about 300 B. C., that provides for assessment of a fine against anyone who adulterates grains, oils, salts, scents or medicinal substances.

References to adulteration of foods can be found in the literature of Rome and Greece. In those countries wine, which was used by rich and poor alike, was often artificially colored and flavored, as well as being grossly diluted. Inspectors were appointed in an attempt to control this practice. Pliny the Elder has one book dealing specifically with wines.[3] Therein he complains that Marmean wine was diluted with water in the proportion of twenty volumes of water to one of wine. He also warns against the wines of Ephesus as being unwholesome because sea water and boiled must are added. Gallic wine also meets with Pliny's disfavor, since:

> . . . the dealers have set up regular factories where they give a dark hue to their wine by means of smoke, and, I regret to say, employ noxious herbs, inasmuch as a dealer actually used aloe for adulterating the flavor and color of his wine.

Grains, and meals made therefrom, were staple articles of diet in the Graeco-Roman world. Whole grains were almost impossible to sophisticate, because of ease of detection. Flours and meals were almost always made in the home, although they were an occasional

[2] Encyclopedia Britannica (1948), Vol. I, p. 187: "adulteration."

[3] Pliny, *Natural History*, Book XIV.

article of commerce. Pliny [4] speaks of the admixture of chalk with flour to increase its whiteness and shortness.

Medieval Period

By the thirteenth century, following the Crusades, manufacture and trade had become more diversified. Commerce in the Middle Ages was characterized by the formation, early in the twelfth century, of tradesmen's or mercantile associations, or guilds. These were voluntary associations, formed for the mutual aid and protection of their members. Guilds developed both in England and on the Continent. They were chartered by the Crown. One of their functions was to maintain the workmanship and quality of their wares. At first, they had their own codes and regulations. Public ridicule against an offender, such as the pillory, or stocks, or immersion in the pond, was a powerful weapon of control. A severer punishment was expulsion from the guild. History records the incident of a butcher being paraded through the streets, his face close to a horse's tail, for selling "measly" meat. The *Domesday Book* tells of a dishonest brewer who was drawn around town in the garbage cart.

After a time, as the guilds became more powerful, their voluntary policing slackened, and local ordinances, or state laws, were enacted in attempts to govern traffic in particular commodities. Filby mentions a London ordinance of about 1400, which provides:

> No poulterer or other person whatsoever shall expose for sale any manner of poultry that is unsound or unwholesome to man's body, under pain of punishment by the pillory, and the article being burnt under him.

This is not as drastic punishment as that meted out in Turkey where, if a baker gave false weight or adulterated his bread, his ear was nailed to his door post.

One of the earliest guilds was that of the "Pepperers." Pepper was one of the valuable spices, and certainly the most important of the spices that comprised the spice trade, due to its use as a preservative of meat. The Pepperers soon took over the grocer, and became the Grocer's Company or Guild. King Henry III of England made the Pepperers the custodians of the official Weights Standards. The members were appointed "weighers" by the Crown. This guild established the profession of "garbelers," the first public food inspectors in England. "Garbel," from an old Arabic word meaning "to sift, or select," was the process of detecting and removing impurities and adulterants

[4] Pliny, work cited, Book XVIII, p. 29.

from spices and similar products, and certifying as to their commercial purity. Garbelers had to face sharp practices from their own guildsmen. In 1316 the Lord Mayor of London forbade the Pepperers from facing the bale "so as to make the end of the bale contain better things than the remainder of the bale." (In 1948 the Los Angeles District, Food and Drug Administration, detained a shipment of cumin seed because the top half of the bags contained good, clean cumin, while the bottom half consisted of sievings, dust and chaff.)

Pike [5] describes an imaginary journey from Dover to London in 1348:

> Here, perhaps, a baker, with a loaf around his neck, was being jeered and pelted in the pillory because he had given short weight. . . . there, perhaps, an oven was being pulled down, because a baker had been detected in a third offense, and had been compelled to abjure trade in the city forever. . . . Pillories were used to punish the sellers of bad meat, poultry and fish, of oats good at the top of the sack and bad below.

Elsewhere Pike says: "False weights, false measures, false pretenses were the instruments most generally in use. No buyer would trust the word of a seller."

Bread, as one of the staples of life, came under legal control rather early in English history. King John, in 1202, proclaimed the first Assize of Bread. This was at first an attempt to fix the price, but later laws regulated quality. The method of price-fixing used by all of these statutes was to vary the weight of loaves of bread according to the cost of a quarter of wheat, keeping the *price* of the loaf fixed. That is, a fixed quantity of bread should be sold for the price of a quarter of wheat. Jones quotes portions of King John's Assize:

> If any default (short weight) be found in the bread of a baker of the city, the first time let him be drawn upon a hurdle, from the Guildhall to his own house, through the greatest streets, where the most people are assembled, and through the streets which are most dirty, the false loaf hanging from his neck; if a second time he shall be found committing the same offense, he shall be placed in the pillory, and remain there at least one hour.

A third offense banished him from his guild. These Assizes were codified by Henry III. A baker or a brewer was fined for violating his respective Assizes the first three times, if not overly serious, but, "if the offense be grievous and often, and will not be corrected, then he shall suffer punishment of the body, that is to wit, a Baker to the Pillory, and a Brewer to the tumbrel." [6]

Laws on the Continent followed the same pattern. Regulations on provisions in France from early times were under supervision of

[5] Pike, *History of Crime in England* (1873) Vol. I, p. 237.

[6] 51 Henry III (1266), as quoted by Filby, *A History of Food Adulteration.*

"Police des Commissaires." Blyth quotes a law on beer enacted in 1292: "Whoever puts into beer bay, pimento, or resin is to be fined 20 francs . . . for such things are neither good nor loyal to put into beer, for they are bad for the head and the body, for the healthy and the sick." Other French ordinances dealt with meals and bread. By one, bakers were forbidden to mill their grain, on the theory that they would have less opportunity for adulteration. Short weights brought corporal punishment and, at times, confiscation of the bakery. An edict of Paris, in 1396, forbade the coloring of butter. The pillory and tumbrel were used, as in England. In 1525 a baker was sentenced by the magistrate to be paraded through the streets in his shirt, with head and feet bare, and with loaves strung around his neck; at various public places he knelt and asked for mercy and pardon of God and King.

Punishment was more rigorous in the early Teutonic States. At times, the punishment was related to the crime, as in Biebrich in 1482. There a vintner who had adulterated his product was condemned to drink six quarts of his own wine. From this he died. An Augsburg wine seller was led out of the city with his hands bound, and a rope around his neck. Two others were branded. Nuremberg enacted a law during the XIV century regulating traffic in honey:[7]

> It has been decreed and strictly forbidden by our aldermen . . . that henceforth none of our citizens . . . may buy or sell any honey except that which has been examined and measured by duly appointed honey inspectors.

The decree further set forth that

> . . . new honey or honey contaminated with brood or other foreign matter may cause sickness in adults and infants, and particularly in pregnant women, it is hereby decreed that henceforth, he be citizen or transient, none may sell or offer any variety of new honey before the birthday of the Virgin Mary.

The penalty for violation was seizure and a fine.

The same city of Nuremberg, in 1444, punished an adulterator of the expensive spice, saffron, by burning him at the stake, over a fire of his own saffron. A little later, two men and a woman were buried alive in saffron.

An ancient breed of English food inspectors, dating back to the fifteenth century, were the "ale-tasters." Blyth quotes the charge given by the mayor to newly appointed ale-tasters of Guilford: "Ye shall well and truly serve his Majesty and this town. Ye shall at all times try, taste, and assize the beer and ale to be put on sale, whether the same be wholesome for man's body, so help you God." The taster used very empirical methods, judged by present-day standards.

[7] 74 *American Bee Journal* 267 (1934).

He not only gauged and tasted the ale; he poured some of it on a wooden bench, and sat on the wet spot in his leather breeches. If his breeches adhered to the bench, it showed that sugar had been added. According to a recent Associated Press dispatch, these ale-tasters are still being appointed in England. A note in the *Penny Magazine* [8] on ale- and beer-drinking in Queen Elizabeth's day mentions the adulteration of ale with rosin and salt, the latter to increase thirst.

Development of Commerce

The sixteenth and seventeenth centuries constituted the era of colonial expansion. Trading vessels roamed the seas, bringing to their home ports the products of the Orient and the New World. A demand for such luxuries as tea, coffee, chocolate and sugar arose. The cruder forms of adulteration were replaced by substitutions of a more skillful and novel character, beyond the scope of the revenue inspectors and health officers of the time to detect. Adulteration had become a fine art. Laws could be enacted, but to little avail. The tools for detection of these more subtle forms of adulteration were lacking. Addision's comments on imitation wines typifies the age:

> There is in this city a certain fraternity of chemical operators who work underground in holes, caverns, and dark retirements. . . . They can squeeze Bordeaux out of the sloe, and draw champagne from an apple.[9]

A century later, Smollett [10] describes the London of 1800 thus: "As to the wine, it is a vile, unpalatable and pernicious sophistication, balderdashed with cider, corn spirit and the juice of sloes." The bread served is a "deleterious paste, mixed up with chalk, alum, and bone-ash, insipid to the taste, and destructive to the constitution." He describes London cream as "the worst milk, thickened with the worst flour into a bad likeness of cream."

There is a record from Queen Elizabeth's time complaining of the adulteration of olive oil with poppy-seed oil. It was in her reign that a law was enacted (1597):

> That if any shall bring into any haven, port, creek, or town of this realm any salt fish, or salt herrings, which shall not be good, sweet, reasonable, and meet for men's meat, and shall offer the same to be sold, then all and every person, owners thereof, shall lose and forfeit to our Soverign Lady all the said unreasonable fish.

There was some attempt made to control the ever-tempting and easy sophistication of beers and wines. In France it was forbidden to mix two different wines, under penalty of confiscation and a fine.

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[8] *Penny Magazine*, June 16, 1838, p. 231.
[9] *The Tatler*, No. 131 (1710).
[10] Smollett, *The Expedition of Humphrey Clinker*.

William and Mary, in England in 1688, decreed through Parliament: "If any merchant-vintner, wine cooper, or other person selling wine by wholesale or retail, shall corrupt, sophisticate, or adulterate any wine . . . such person forfeit the sum of £300 for every such offense." In the reign of William III, in 1701, a law was passed forbidding the use in beer and ale of "sugar, honey, foreign grains, Guinea Pepper, or the liquor called essentia bina (a very dark caramel), or cocculus indicus or any unwholesome ingredients." (N. b., cocculus indicus contains the poisonous substance picrotoxin.)

An act of Charles II provided: "No butter which is old or corrupt shall be mixed or packed with any butter which is new and sound, nor any whey butter shall be mixed or packed with butter that is not made of cream."

English laws in this period dealt more with articles of luxury. Increase in public revenue was of more importance than an increase in public health. There were two devices used. One was to give a monopoly to a private company, or to the crown; the other was to impose an excise tax. Spices, tea, coffee, cocoa and liquors were taxed in this way.

Queen Elizabeth, in 1601, chartered the East India Company in an effort to break into the spice trade monopolized by Portugal and, later, by Holland. In 1670 the East India Company entered into the tea business. Its monopoly in tea lasted until 1833. Ukers [11] states that tea was adulterated in China, and further adulterated by the home merchants. The importers at times added iron filings, clay and gypsum to increase weight. In England, foreign leaves and exhausted tea leaves, as purchased from hotels and coffee-houses, were used as "stretchers"; occasionally the spent leaves were doctored with extracts of bitter leaves like elder or catechu.

During the time of King George I a law was passed forbidding mixing tea with any other substance under penalty of seizure, and £100 fine. The law was strengthened by George II in 1730. The preamble to this law recited:

> . . . that several ill-disposed persons do frequently dry or manufacture very great quantities of sloe leaves, licorice leaves, used tea leaves, or leaves of other plants, trees, or shrubs, in imitation of tea; and do likewise color, stain or dye such leaves, or mix tea with terra japonica, sugar, molasses, clay, logwood or other ingredients, and do sell or vend the same as true tea, to the prejudice of the health of his Majesty's subjects, the diminution of the revenue, and to the ruin of fair trade.

[11] Ukers, *All About Tea* (1935).

In addition to damage to health and revenue, a 1777 law attributed injury and destruction of timber, woods and underwoods, and encouragement of idleness to the traffic in adulterated tea.

Ukers quotes a pamphlet written in 1785 by Richard Twining, a noted merchant of the day, to the effect that ash leaves were sun-dried, baked, and trodden on a floor, then steeped in copperas with sheep's dung. The resultant product was used to adulterate tea. The Chinese made a spurious tea for export appropriately labeled "Lie Tea." It was made from tea grounds, tea dust, and foreign leaves, molded into little masses with the aid of gum, then painted to resemble gunpowder tea. Even after passage of the general food laws in England in 1860 and 1875, such large quantities of Lie tea were imported through London that a special tea examiner was appointed for that port.

Coffee has a somewhat similar history to that of tea. In fact, it came to the attention of tax collectors, in England at least, a few years before tea. It was a beverage for the rich, and hence fair game for the Exchequer. A law of 1719 prohibited coffee roasters from adding water, grease, butter or such like material to coffee for the purpose of increasing its weight, since by so doing they "do damnify and prejudice said coffee . . . to the prejudice of his Majesty's revenue, the health of his subjects, and to the loss of all honest and fair dealers." The fine was £20. By 1803, more modern forms of adulteration were used, and the amended law forbade the addition of roasted peas, beans or grains.

Legislative Period, 1800 to Date

We now enter a period of history that has been differently characterized by two schools of writers. There was an unmistakable increase in reported adulterations of foods. One set of writers ascribed this condition to lowered ethical standards in business and government. The other attributed it to the sudden development of the science of analytical chemistry. Two things contributed largely: the development and use of the analytical balance and the microscope. The latter instrument enabled chemists to identify foreign substances in foods. It was particularly valuable in the recognition of plant material used for the adulteration of other plant material, for example, chicory in coffee. Quantitative chemistry now enabled analysts to identify and determine amounts of adulterants.

Although recognizable adulteration increased with the increased skill of detection, controlling laws did not keep in step. Such laws as did exist, as we have seen, were for the protection of state revenue.

Some public clamor for protection arose. In response, the ancestors of Departments of Health were established, such as the Conseil de Salubrite established in Paris in 1802. Laws to curb adulteration of one particular food cured the specific evil for the nonce, then died of inanition. Such was the act passed in England in 1816 which made the use, or mere possession, by a brewer, of molasses, honey, quassia, vitriol, cocculus indicus, Grains of Paradise or opium as a substitute for malt or hops a crime. The penalty was forfeiture, plus a fine of £200. A similar law, passed May 19, 1829, in Belgium, forbade addition of copper sulfate, zinc sulfate "or other poisonous ingredients," to bread, under penalty of fine and imprisonment.

The leaven of revolt existing in the early nineteenth century brought about a public clamor against existing adulteration of foods and medicines. Books, pamphlets and magazine articles reflected this unrest. The first pioneer on record to make this his life work was Frederick Accum, a German chemist and pharmacist, who set up a laboratory in London in 1793. In 1798 Accum began a series of articles in *Nicholson's Journal*, "Discourse on the Genuineness and Purity of Drugs." In 1820 he published his most celebrated book, *Treatise on the Adulteration of Foods and Culinary Poisons, Exhibiting the Fraudulent Sophistications of Bread, Beer, Wine, Spiritous Liquors, Tea, Coffee, Cream, Confectionery, Vinegar, Mustard, Pepper, Cheese, Olive Oil, Pickles, and Other Articles Employed in Domestic Economy, and Methods of Detecting Them.* The cover leaf of the book depicted a spider web, bordered by snakes, and bearing the motto "There is Death in the Pot," from II Kings, 2:40. The book, therefore, became known by the public as *Death in the Pot.* An interesting article on the life of Accum has been written by C. A. Browne.[12]

Accum published names and addresses of merchants selling adulterated foods and drugs. A later book, inspired by the public success of Accum's work, was published anonymously in 1830 under the title *Deadly Adulteration and Slow Poisoning Unmasked; or Disease and Death in the Pot and Bottle.* The author was given as "An Enemy of Fraud and Villainy." These two books listed many dangerous additions to foods. Accum told of a woman who passed away the time while at her hairdresser by eating pickles greened with copper sulfate. She became ill and finally died. He also told of illness caused by eating cheese colored with annatos, which had been in turn mixed with vermilion and red lead. The author of *Death in the Pot* listed the follow-

[12] 2 *Journal Chem. Education* 829 (1926).

ing adulterants of gin: oil of vitriol and capsicum to impart pungency; extracts of orris, and angelica to give body; ether to enhance the alcoholic taste; turpentine to give it strength; and arsenic to promote thirst, so that the consumer will drink more of the mix. Similarly toxic ingredients are listed as adulterants of beer.

Other books and pamphlets, some in attempted refutation of these charges, followed. One of the most curious was *The Domestic Chemist —Instructions for Detecting Adulteration,* published anonymously in 1831. This listed 48 substances said to have been used as adulterants of beer and ale, including such poisonous substances as henbane, cocculus indicus, nux vomica, poppy extract or opium, Grains of Paradise and sulfuric acid. He reports finding bone ash, plaster of Paris, gypsum and alum in flour, and litharge in brandy and wine. Filby has stated that there is no foundation in fact for some of these accusations.

In the United States, a Dr. E. D. Foust published an article [13] on "Original and Select Observations on the Detection of Adulterations." He was more interested in drugs and medicines, but mentioned finding poppy seed oil in olive oil, and sulfuric acid in vinegar. Hureaux, in France, compiled an alphabetical dictionary of foods and drugs, listing the adulterants found. He reported butter cheapened by addition of chalk, potato starch or meal, and veal fat. Milk was usually skimmed, with starch paste, gelatine or gum added to restore its body, and colored with a yellow dye to conceal the blue tint caused by skimming. Coffee, according to Hureaux, may be adulterated by admixture with exhausted coffee grounds, toasted bread, browned acorns, or sugar beet waste, but the commonest substance used is chicory. French law prohibited use of any mineral pigments in candy except Prussian Blue or Ultramarine.

One of the earliest standards for a food is included in a British law of 1836. This defines bread as the product made from

> . . . flour or meal of wheat, barley, rye, oats, buckwheat, corn, peas, beans, rice or potatoes, or any of them, and with salt, pure water, eggs, barm (brewer's yeast) leaven, potato or other yeast, and mixed in such proportion as they (the makers) shall see fit, and with no other ingredients or matter whatsoever.

It is quite possible that many of the horrible adulterants mentioned by the more polemical writers were due to carelessness and poor technique. Some were undoubtedly wrongly identified through faulty analysis. This could not be said of the author of a series of

[13] 13 *American Journal of Science and Arts* 70 (1831).

reports that started in England in 1851-1855. Dr. Wakley, editor of the powerful medical journal, *The Lancet*, became acquainted with a Dr. A. H. Hassall, a physician, who had made a hobby of the microscope. He had written a paper for the Botanical Society of London on adulterations found in coffee, using the microscope as his chief tool, but also employing chemical methods. Wakley persuaded Hassell to investigate generally the question of adulteration of foods, promising that he would publish the reports in *The Lancet*. A Sanitary Commission was appointed by Wakley, with Hassall as its investigator. The reports, as published during 1851 to 1854, were republished in book form in 1855. Hassall published a second book in 1857. This was chiefly a laboratory manual, extensively illustrated with drawings showing the appearance of authentic food structures, and substitutes thereof, as seen through the microscope.

Hassall's articles listed names and addresses of merchants selling adulterated foods. His investigation extended throughout the major cities of England. Much newspaper and magazine publicity was given to the *Lancet* reports. One reviewer [14] said:

> To such a pitch of refinement has the art of fabrication of alimentary substances reached that the very articles used to adulterate are themselves adulterated, and while one tradesman is picking the pockets of his customers, a still more cunning rogue is, unknown to himself, deep in his own.

An idea of the extent and scope of food adulteration as practiced in England in 1850 may be seen from the following table, summarizing Hassall's findings on particular foods:

Food	Number of Samples	Number Adulterated	Adulteration Found
Coffee	145	127	Chicory, roasted wheat, corn, acorns or beans, iron oxide, roasted wurzelmangel, coconut shell
Chicory	75	30	Roasted wheat, acorn, bean or carrot, sawdust, Venetian red, sand
Sugar, brown	72	40[a]	Grape sugar, potato flour, tapioca, starch, grit
Bread	74	74	Alum
Flour	8	4	Alum
Cocoa	56	48	Cocoanut shell, colored earth, cocoa shell, starch
Oatmeal	30	16	Barley meal, rubble (husk)
London milk	26	11	Water, fat skimmed off, formaldehyde
Mustard	42	42	Flour colored with turmeric, mustard hulls

[a] In addition, all contained sugar mites, many contained mold.

[14] 96 *Quarterly Review* 460 (March, 1855).

Food	Number of Samples	Number Adulterated	Adulteration Found
Cayenne pepper	28	24[b]	Red lead, cinnabar, ochre, turmeric, mustard hulls, rice
Vinegar	61	32	Sulfuric acid up to .6 per cent
Green tea	50	50	Exhausted tea colored green, mineral pigments, foreign leaves

[b] Twelve contained red lead.

As an indication of the extent of dilution of cocoa with cocoa shell, Mitchell quoted excise figures showing that 612,122 pounds of cocoa shell and 4,000 pounds of cocoa were imported into Ireland during one year.

Hassall, with a wry sense of humor, quoted the merchant's advertisements along with his analysis. A "Fine Java Coffee" contained very little coffee, being chiefly chicory and roasted potato. A shop had a large sign "Genuine Coffee—No Adulteration." The sign warned the public "against the present pernicious practice pursued by many grocers in adulterating their coffee with dog-biscuit, roasted beans, chicory and tan." Coffee purchased here contained a large quantity of chicory. One of the dealers listed by Hassell wrote to *The Lancet*, complaining that the purchaser should not ask for "coffee" but for "pure coffee," if he did not want a mixture of coffee and chicory. Another coffee merchant, following Hassall's first report on coffee, put a coffee mill in a large window so that "the most credulous cannot but feel satisfied that they have a genuine article." Here, too, Hassall purchased coffee that was mostly chicory. The wierdest adulterant reported for coffee is that of roasted ox- or horse-liver. The roasted, ground liver was sold to low-price coffee shops for 4d to 6d per pound.

Pure coffee was similarly hard to find in the United States. Battershall, as late as 1887, reported that of 151 samples of ground coffee purchased at random, 69, or 41 per cent, were adulterated.

Spice grinders sold four grades of mustard. The names of these grades—"seconds," "fine," "superfine," and "double superfine"—are reminiscent of the size designation of California olives of today. Hassall found all four grades adulterated.

Tea, being subject to an excise tax, was particularly subject to adulteration. Hassall, reporting various foreign leaves, and mineral pigments which he found in tea, commented that there were eight dealers in London alone, in 1843, that bought up exhausted tea leaves

from hotels and coffee-houses, at 2½d a pound. These grounds were mixed with gum solution, redried, catechu added for astringency, and "faced," with appropriate pigments, to resemble either black or green tea, as desired. He observed that the pigments used by these dealers were more injurious than those used by the Chinese in the original sophistication of the tea. A tea seized in London by excise authorities contained 35 per cent copper carbonate, and another in Manchester was colored with potassium chromate. Inspectors found copper arsenite, lead chromate and indigo on the premises, evidently to be used for coloring tea. Battershall, who was customs chemist for the Port of New York around 1880, analyzed several preparations employed in Japan for "facing" tea. These included soapstone, gypsum, Prussian Blue, indigo and turmeric. He also reported the same trade in exhausted tea leaves by New York manipulators that Hassall had reported earlier in England. In 1883 the United States passed the Tea Adulteration Act. The United States Tea Examiner's first report, covering March through December of that year, shows that about 4,000,000 pounds of tea were examined and 325,000 pounds, or 8 per cent, rejected. The official report of 1950, under this act, covers 106,126,494 pounds, of which only 140,202 pounds, or about .1 per cent, were refused entry.

The food that was adulterated with the most complete disregard for health was candy. In Hassall's time aniline dyes were not yet in use; aside, then, from the few vegetable dyes available, manufacturers of colored candies were forced to use mineral pigments. These are, for the most part, compounds of lead, arsenic, copper, mercury and chromium, all highly toxic. Hassall analyzed 100 samples. Fifty-nine of these contained lead chromate, 12 were colored with red lead, six with vermilion (mercury sulfide) and four with white lead. At times, several of these pigments were used in one candy. As late as 1875, these poisonous pigments were in use in this country. Boards of health from various states examined 48 samples of yellow or orange-colored candies. Of these, 41 contained lead chromate.

Battershall mentions a "rock-and-rye" candy which was quite popular among school children. This proved to be a mixture of glucose, flour and fusel oil.

As a result of the expose by *The Lancet*, Parliament appointed a committee to investigate the extent of adulteration. Food manufacturers furnished additional evidence to committee hearings. Testimony of two illustrates the trend. One witness testified he had roasted

700 tons of carrots for admixture with chicory. A cocoa roaster gave the formula for his best soluble cocoa. In his own language, this was: cocoa 42, lump 42, white and red, 52. In this "lump" represents sugar, "white" is starch, and "red" is red oxide of iron for color. Cocoa comprises only 30 per cent.

The committee concluded that adulteration widely prevailed, that public health was endangered, public morality tainted, and pecuniary fraud committed on the whole community. Some public agitation, along with a few food-poisoning incidents, kept Parliament interested. Jones mentions a lecturer in 1860 who described the results of serving a green-colored pudding at a public dinner. The caterer had asked a druggist to compound a green color for him, and was given copper arsenite. As a result, two or three victims died. The speaker also mentioned buns colored with arsenic sulfide, a yellow pigment, through which two children almost died. The druggist furnishing the coloring matter to the baker readily admitted he made a mistake; he had intended to furnish lead chromate! The result was the passage by Parliament of the Adulteration of Food and Drink Act in 1860, the first general food law of England. This was replaced in 1875 by the Sale of Food and Drugs Act.

These acts set up the jobs of public analysts, now prevalent in the United Kingdom. These analysts, who were appointed at the requests of city and county governments, tested foods submitted by local health officers or by citizens. The public was slow to take advantage of the opportunity. A. D. Letheby, appointed Analyst for the City of London in 1860 said he had only four requests for analysis the first quarter—one milk, two bread, and one mustard sample. The milk was watered, the mustard contained flour and turmeric, and one of the breads contained rice flour and alum. The scheme proved workable, as shown by the Ministry of Health's Report for 1935. That year 140,000 samples were examined by public analysts, and 7,451, or 5.3 per cent found violative. Over 5,500 of these were milk.

These laws did not save British citizens from one of the most famous food-poisoning epidemics in history, that of the arsenic-bearing beer that affected some 6,000 people in the Manchester-Sheffield area, with at least 70 deaths. This epidemic offered a remarkable instance of prophecy by an expert food chemist. In 1879, Alexander Blyth, in his Manual of Practical Chemistry, called attention to the possibility of contamination of beer by arsenic. In 1900, this Manchester epidemic confirmed the prophecy. The arsenic was traced

to one particular brewery, and then to brewer's sugar, or glucose, supplied by a Liverpool firm. This sugar, containing up to 3.2 grains of arsenic per pound, was made by hydrolizing starch with sulfuric acid made from arseniferous pyrites. It may be noted that a Royal Commission appointed to investigate the tragedy recommended that a tolerance be set on beer or other liquid foods at .01 grain of arsenic per gallon, and on solid foods at .01 grain of arsenic per pound.

The legislative history of other countries went through similar cycles. A compilation of laws of other countries made by the British Foreign Office was published in several issues of a food journal.[15] The United States Commissioner of Internal Revenue made a similar, though less extensive, inquiry.[16]

A German investigator, as quoted by a German correspondent to the *Nation*,[17] had 17 brands of German chocolates analyzed: Nine contained no chocolate, only ground cocoa, browned flour and sugar; two others had 5 per cent and 10 per cent chalk, respectively. The German Empire passed a general food law in 1879. The individual German states also had local codes. France passed a general food law rather early—1851. In 1855, it was amended to include beverages. The Netherlands law was even earlier (1829), but it covered only the addition of poisonous ingredients.

Attempts to make illicit profit sometimes takes devious ways. One illustration will suffice, taken from the Report of the Government Analyst, New South Wales, 1939.[18] It was the practice of many hotels and bars in that country to salvage waste beer that drips from taps or overflows from glasses. In some cases, the waste pipe from drip trays, apparently connecting to drains, were by-passed through a pipe leading to a concealed cask. This recovered beer—often contaminated with viable yeast and mold, dirt, and even flies and maggots —was bottled and sold. The State controlled this practice by requiring that all waste receptacles contain sufficient methyl violet to impart a distinct violet color to the beer. The analyst reported that this was an effective deterrent.

The history of national food legislation in this country is too well known to repeat here. It will suffice to trace the development of law through various state reports. The first law on record in the United States was that passed by the Legislature of Massachusetts in 1784.[19]

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[15] *The Food Journal* (England, 1870-1871).

[16] Report: Commissioner of Internal Revenue, 1889.

[17] 26 *The Nation* 129 (1878).

[18] 66 *The Analyst* 377 (1941).

[19] *Food Journal* (December 1, 1870), p. 562.

This punished by a fine of not more than $300, or imprisonment for one year, any seller of diseased, corrupted or unwholesome provisions. Coming to more modern times, during 1865-1900 many states passed general food legislation. Fines and punishment at times were severe. The Georgian Code (1867) [20] provided that "any baker, brewer, distiller, merchant, grocer, or other person selling unwholesome bread, drink or pernicious liquors, *knowing them to be so,* shall upon conviction be fined, imprisoned, or both." It goes on to say that accessories after the fact may be fined up to $1,000, jailed up to six months, whipped up to 39 strokes, or made to work on a chain gang up to one year.

Massachusetts, New York, Michigan, New Jersey and Rhode Island, among others, passed food laws during this period. Considering the variety and extent of adulteration occurring in the state, the Legislature of Massachusetts expressed unconscious humor when, in 1882, it placed enforcement of the state's Food and Drug Act in the hands of "The State Board of Health, Lunacy, and Charity." Wharton [21] and Battershall have reviewed the annual reports issued under these early state laws. They report formaldehyde and boric acid in milk; maple syrup adulterated with cane sugar; watering of milk; sophistication of tea, coffee and spices; addition of glucose to honey; and so forth.

Some startling figures are given by Battershall, dealing with the period around 1880 as to the extent of adulteration. Over 73 per cent of the milk of Buffalo was watered, 69 of 171 samples of ground coffee collected in New York were adulterated, 71 per cent of the olive oils examined in New York and Massachusetts were mixed with cottonseed oil which had been shipped from the United States and returned as "olive oil." Forty-six per cent of candy samples collected in Boston contained mineral pigments, chiefly lead chromate. As late as 1906, Kansas reported that 95 per cent of the maple sugar and syrup samples examined were adulterated. Even in New Hampshire, the home of the sugar maple, the state board of health found only 21 genuine maple sugar or syrup samples out of 41 tested.

These conditions led inevitably to enactment of federal law, first the act of 1906 and, later, the present act of 1938, as amended. Accumulating notices of judgment under these acts show that adultera-

[20] Publication cited, footnote 19 (November 1, 1870), p. 507.

[21] *Historical Meeting to Commemorate Fortieth Anniversary of Federal Food and Drugs Act* (1946), p. 67.

tion of foods still occurs, at times through carelessness or ignorance, but too many times by intent. This is a matter for future historians to record. **[The End]**

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AN OBJECTIVE APPROACH TO

The Problem of Developing Grades and Standards of Quality

By AMIHUD KRAMER

Dr. Kramer, Professor of Horticulture at the University of Maryland, Suggests a Step-by-Step Procedure for Developing Grades and Standards of Quality Which Would Make Maximum Use of Recent Research Developments

GRADES AND STANDARDS of quality have been developed over the last 50 years or more by trade and consumer groups, and federal and local governmental agencies.[1] These standards were developed for each commodity as the need arose, so that at the present time there is a large number of commercial and governmental grades and standards available for many fresh and processed food commodities. In many cases they are of inestimable value to the food industry, as evidenced by the huge volume of food that is marketed on the basis of such grades and standards. In some instances, however, standards of quality which do not meet all the requirements of food producers and users are recommended or promulgated. This may occur when standards are developed under emergency conditions, when it becomes necessary to have working standards available within a short period of time and with the expenditure of very limited resources.

It is generally agreed that standards of quality are important enough to warrant thorough scientific investigations which would lead to the most precise standards obtainable, based on the best available scientific methods.

This paper consists of a suggested outline describing a step-by-step procedure which may be followed in developing grades and standards of quality in accordance with orderly research procedures, where maximum use would be made of recent developments of physical,

[1] Spangler, R. L., *Standardization and Inspection of Fresh Fruits and Vegetables* (United States Department of Agriculture Miscellaneous Publication, 1946), p. 604.

chemical, biological and statistical tools, and only the unavoidable minimum left to personal judgment of the individual inspector. Especially in the case of standards that are to be legally enforced is it essential to have objective methods based on sound scientific principles and procedures, since in the absence of such objective standards, enforcement would be very difficult.

Quality has been defined recently [2] as the "composite of those characteristics that differentiate individual units of a product, and have significance in determining the degree of acceptability of that unit by the user." Hence, standards of quality should have for their goal the establishment of precise and accurate specifications to characterize the quality factors of any given lot of material. Such specifications may be useful to the grower of the raw material, the processor, the broker, the distributor, the retailer or the consumer.

The engineer, concerned with the manufacture of a machine constructed of inert material, using precision tools and measuring devices, frequently complains of the difficulties involved in setting up specifications for his product. His difficulties are minor, compared to those of the food technologist who deals with inherently variable biological material, and whose ultimate measuring device is human evaluation. Thus, it is logical to make the following assumptions: First, because of their natural variability, food specifications cannot be too narrow and rigid; and, second, the suitability of any objective, that is, physical or chemical method must be evaluated by its agreement with human evaluation as measured by expert or consumer panels.

Two principles are involved in any type of measurement—namely, precision and accuracy—where precision is the ability to duplicate results, with one instrument or with different individual units of the same instrument, while accuracy refers to the degree to which the instrument or procedure reflects human evaluation. Precision may be measured statistically by the coefficient of variability. Thus, for example, Walls, Kemp, and Stier [3] found that the coefficient of variability for tenderometer readings on raw peas was 1.56 per cent, and for texturemeter readings, 7.5 per cent. Accuracy may be measured statistically by the coefficient of correlation, where objective values are correlated with human evaluation in the form of a testing panel of

[2] *Proceedings of Conference on Marketing*, U. S. D. A. and Agricultural Experiment Station, Michigan State College, East Lansing, July, 1951.

[3] Walls, E. P., Kemp, W. B., and Stier, H. L., *Practical Use of Methods for Determining the Grade of Peas from the Raw Product* (Maryland Agricultural Experimental Station, Miscellaneous Publication, 1940), p. 709.

judges. A correlation coefficient of 1 indicates perfect accuracy. In general, .8 is considered acceptable, although .9 is much more desirable.[4] Ordinarily, greater precision tends towards greater accuracy, although that is not always true. For example, the coefficients of variability for the alkali-digestion and blendor methods of determining fiber in green beans were found to be 4.2 and 8, respectively; however, the correlation coefficients were .75 and .82, respectively. Thus, in this particular case, the less precise blendor method was in closer agreement with human evaluation, although it was a less precise procedure than the alkali-digestion method.[5]

It is obvious that the main advantage in objective methods lies in the potential improvement in precision or duplicability. In other words, an instrument or chemical procedure is more likely to provide identical results for identical samples of food under conditions which might affect the precision of a human judge, such as a lapse of time, differences among individual judges, and the state of health and discriminatory ability of the judge, etc. Less advantage may be expected for the objective method in terms of improved accuracy, since the accuracy of the objective method as such is measured in terms of agreement with human evaluation, except in the sense that the evaluation of one particular judge may not necessarily be in close agreement with human evaluation as a whole. Thus, in one instance where ten judges scored samples of tomato juice for color, the correlation coefficients between each judge's score and the average score ranged from .57 to .91, while the correlation between the average score and the best objective method was .94. One additional advantage is inherent in the objective method, which is the automatic elimination of the human element. Thus, unbiased values are provided, whereas human evaluation is always, whether consciously or not, subject to bias.

The development of grades and standards of quality may proceed as follows:

(1) Definition of the quality characteristic to be measured.

(2) A search for methods of measurement.

(3) Correlation with human evaluation.

(4) Selection of best method or methods.

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[4] *Proceedings of Conference on Methodology in Palatability Testing* (Mim., Bureau of Human Nutrition and Home Economics, United States Department of Agriculture, January, 1950).

[5] Kramer, A., "Objective Testing of Vegetable Quality," 5 *Food Technology* 265-269 (1951).

(5) Improvement in simplification and precision of the selected method.
(6) Validation of the method.
(7) Establishing a scale.
(7A) Integration by weighting of quality characteristics.
(8) Application.

Definition of Quality Characteristic to Be Measured

The first question which must be answered is: Exactly *who* is to select and define the quality characteristics? Should it be the ultimate consumer, or an impartial governmental or institutional agency? Obviously, the producer, the user, and any regulatory agency involved all have an interest in this definition and should all be consulted. Using sweet corn grown for the cannery as an example, the grower and the canner are the producer and the user, respectively. The ultimate consumer is not involved directly, although indirectly he may influence the interest of the canner in that the canner would desire to have a standard by which he could measure the extent to which the raw corn offered to him will be accepted by the consumer after it has gone through the canning and market operations. Thus, the canner should know what factors of quality are of importance to the consumer and in that respect be the consumer representative.

The next problem is an analytical one, where the over-all quality must be broken down into its component characteristics. Wherever possible, these characteristics should be broken down and defined in such a way that it may be possible to measure each characteristic by a physical instrument or chemical procedure.

Once the characteristics of quality have been defined, a thorough survey of literature should be made not only of previous attempts to measure these quality characteristics for the same product, but also a review of developments in related fields. Engineers, physicists, chemists and commodity specialists should be consulted at this time. This effort should result in a number of possible methods which may be studied.

Correlation with Human Evaluation

These possible methods should be tried on a limited number of samples (10 to 50) showing large variations in the quality characteristic under study. At this point it should be possible to discard many of these suggested methods which are lacking in precision, or which show little promise of reflecting human evaluation.

The remaining procedures should be tested on a larger number (100-1,000) of selected samples varying across the entire range of quality. It is more efficient to select these samples not by a random survey method where a very large portion of the samples would cluster about the average quality, but to attempt to obtain an equal number of samples across the entire quality range. A duplicate set of samples or, where possible, the identical set of samples should be submitted to a sensory test panel consisting of trained judges. These judges should be instructed to rate these samples on an arbitrary numerical scale for differences rather than preferences. Thus, for example, if the hardness of peas is the factor under study, the judges on the sensory panel should rate the peas on a degree-of-hardness scale alone, and not rate the samples for the degree of hardness which they prefer.

The data obtained by the use of these methods may then be correlated with the test-panel scores. The higher the correlation coefficient, the greater the accuracy of the method in reflecting human evaluation. At this point it may be possible to select the best method for measuring the specific characteristic of quality if one of the tests under consideration shows a very high correlation with the sensory panel and is significantly higher than a correlation between any of the other tests and the sensory panel. Very frequently, correlations of this nature assume a logarithmic or other curvilinear relationship so that it may be necessary to transform data in order to obtain the best possible correlation. For example, when a correlation was calculated for the per-cent fiber in asparagus and fibrousness as measured by a sensory panel and a linear relationship was assumed, the correlation was only .85, as compared to a correlation of .93 when the per-cent fiber data were transformed to logarithms.

The experience of this laboratory has indicated that a correlation between two sensory panels rarely exceeds .94. Hence, it is assumed that a correlation of .94 rather than a correlation of 1 indicates practically perfect agreement between any given test and human evaluation. For this reason it may be assumed that any method showing a correlation of .90 or better is an excellent indicator of human evaluation. Similarly, a correlation of .80 or better is considered satisfactory for use, although a higher correlation is desirable. If the correlation fails to reach .80, the method is considered unsatisfactory and that particular characteristic of quality may not be measured by any but sensory methods.

It is possible, perhaps because of insufficient definition of the characteristic involved or because the characteristic simply cannot be broken down sufficiently, that a combination of two or more physical or chemical tests may be used to obtain a satisfactory correlation with human evaluation. This was found to be the case with the factory of "maturity" in sweet corn where the tests of moisture, pericarp, and kernel size, singly, did not meet the requirements for a correlation of .80 or higher with human evaluation, when varietal and seasonal differences were disregarded. However, the multiple correlation between all three tests and human evaluation was found to be .93.

Improvement in Simplification and Precision of Selected Method

Assuming a satisfactory method or methods were found to measure a given characteristic of quality, it is desirable that the surviving method be as precise, simple and rapid as possible. At this point, therefore, each step in the method should be examined carefully to see whether it can be omitted or modified with the view of improving speed and simplicity and yet retain maximum precision. The relative precision of the method is extremely important in grading operations, since it is frequently desirable to perform a minimum amount of replication. Thus, for example, four replications would need to be averaged in order to obtain the same precision with a method having a coefficient of variability of 4 per cent as compared to a single determination by a method having a coefficient of variability of only 2 per cent.

Thus far the study may include only commercial samples whose complete history may not be known. At this point it is necessary to check for what amounts to loopholes. It is possible that under a given set of conditions, results obtained by the method will not reflect human evaluation and that this particular set of conditions was not met with for any considerable number of samples tested previously. It is, therefore, necessary to examine all the factors that might possibly have a differential effect on the method, and human evaluation. For example, hormone-treated snap-bean pods appear to develop normally while the seed does not develop. If the objective method in this case consists of a determination of per-cent seed, then beans so treated would grade "very young" because of the low seed development, while actually the pods are large and woody and appear considerably more mature to human judges.

This step in the procedure, therefore, requires complete control over the material from the seed stage to the final processed product, and a design where variables in the factors that might affect the quality measurement are introduced experimentally.

Establishing a Scale

Assuming that a method of adequate precision and accuracy has been developed which is also sufficiently rapid and simple for routine use, it is now necessary to establish a scale by which values obtained by means of the proposed method may be translated in terms of quality that will have meaning to the producer and user. Thus, for example, an alcohol-insoluble-solids value of less than 20 per cent may mean fancy whole kernel canned sweet corn, while a value of 21 per cent may mean only extra standard quality, and a value of over 27 may indicate substandard quality. The establishment of such a scale again requires the use of a sensory-test panel. Whereas before a "difference" panel was employed, a "difference-preference" panel is required at this point. Thus, this panel would grade on a numerical scale, but should indicate preferences as well as differences, and the most desirable samples would be rated as highest. The actual numerical scales used by the panel may differ for different purposes. Where values above the substandard range are to be established, it may be convenient to use a ten-point scale, where panel members may indicate substandard value by the figure 1; standard by 2, 3 or 4; extra-standard by 5, 6 or 7; and fancy by 8, 9 or 10. The equivalent values for the objective method may be obtained from the regression equations calculated from the objective and panel values obtained for the same set of samples.

Because of the obvious importance of this panel which would establish the grade brackets for each characteristic, it should be truly representative of the producers and the users of the product involved. For federal standards, it should include representatives from each production area, and from each group having an interest in the standards. For nonperishable commodities it may be practical to have a separate panel in each region to whom identical sets of samples would be submitted. The local panel results could then be compiled into a national average.

Integration by Weighting of Quality Characteristics

In many instances it is not necessary or desirable to attempt to combine several characteristics of quality into an over-all quality

value any more than it is necessary to combine individual nutritive contents into an over-all nutritive value. In some cases, however, attempts are made to integrate separate quality characteristics into an over-all quality standard. This is done by assigning relative weights to each of the quality characteristics in accordance with its importance. This is done ordinarily in the present United States Grades and Standards by assigning a given number of points to each characteristic on the basis of the experience and judgment of the individual responsible for establishing the standard. This weighting can be done objectively by the use of multiple correlations where the individual tests of quality characteristics may be correlated against an over-all grade provided by a "difference-preference" panel. The relative weights, however, would be calculated statistically from the above correlations and regression equations, so that conclusions would be more objective in that respect. Another result of these calculations would be the coefficient of determination (R^2) which should indicate how much of the over-all quality is covered by the characteristics measured.

Application

After the methods have been developed and the relative importance weighed and grade brackets established, the standard is ready for application. No matter how precise and accurate the testing procedure may be, it will not be satisfactory if the lots to be tested are not adequately sampled. It is, therefore, necessary to work out statistically an adequate sampling procedure which will insure that the sample removed from the lot will not be overly destructive or too time-consuming, but yet sufficiently precise as an indication of the quality of the lot.

It may be found that the standard developed for a particular product may not be practical to apply in its entirety under actual inspection conditions. It may be possible to develop some short-cuts which the individual inspector might use, and the complete procedure may be reserved for supervisory purposes.

Summary

A procedure is outlined for the development of grades and standards of quality which would take maximum advantage of recent research developments and, thus, result in grades and standards based largely on objective methods, and only the unavoidable minimum would remain subject to the individual inspector's judgment.

[The End]

Use of Chemical Additives in Foods

Report of the
Food Protection Committee,
National Research Council

FOODS are themselves composed of chemicals, such as carbohydrates, fats and proteins. Chemical additives are employed to improve nutritional value, enhance quality or consumer acceptability, preserve food or make it more readily available. In addition to intentional additives, there may be incidental additives, such as pesticides, which may be introduced into foods during growth and processing, and may remain in the food in minute amounts. These chemicals are essential in the production and processing of many crops.

There need be no hazard in the use of chemical additives, provided adequate scientific research programs are carried out prior to use. The fact that a chemical is toxic does not mean *per se* that its proper use as an additive will entail a hazard. The distinction must be made between hazard and toxicity. Toxicity is the capacity of a substance to produce injury; hazard is the probability that injury will result from the use of the substance in the quantity and in the manner proposed. Chemical additives should not be permitted in a food until their safety for a given food use has been established beyond a reasonable doubt, as judged by competent experts.

Although there is no justification for the exaggerated viewpoints that have been widely circulated, it is true that so many new chemicals have been introduced during the past ten years, and still others are in immediate prospect, that it is well to examine existing practices and information based on research. There are four federal agencies responsible for the protection of the public by their administration of different laws. These agencies and other federal and state agencies are engaged in research pertinent to the chemical-additive problem. In addition, industry is supporting extensive research programs designed to assure the availability of facts required as a basis for determining the safety or hazard of individual chemical additives. No reputable manufacturer will add any chemical to food when a hazard to the public health is involved.

Contrary to some ideas that have been circulated, reliable food processors have not reduced the nutritional quality of our foods or created inferior products through the use of chemical additives. Actually, the quality and sanitary characteristics of our foods have been improving. Likewise, there is no evidence that consumption of foods resulting from the use of the new chemicals in crop production or in the processing of foods have created mysterious disease epidemics or endangered the health of people.

Use of Chemical Additives in Foods

The American people now enjoy the most abundant and varied diet of any nation in history. This is possible because of improvements in food production and technology. Chemicals have played an important role in many of these improvements.

When this country was settled, nine farm workers produced enough food for themselves and one city dweller. By 1940, one farm worker could produce enough for himself and nine others. Today the ratio has further increased; 14 urban dwellers now depend on each farm laborer. This efficiency has been achieved, even though there have been increasing difficulties from disease and insect pests and the depletion of three quarters of a million acres of fertile land by soil erosion.

The food processors have matched the progress on the farm by creating new industries for food preservation. Today there is available in every community a steady supply of fresh fruits and vegetables and processed products that retain practically all of the nutritive quality and appetizing flavor of the fresh product. Dairy products and baked goods are distributed regularly to rural and urban customers.

These achievements were made possible by the discovery of many new scientific principles in biology, chemistry and engineering, and by the invention of new machinery. The public has recognized the obvious advantages resulting from the use of labor-saving machinery such as the tractor, corn picker, pea sheller and frozen food locker. Many people, however, have not been aware of the importance of chemicals in this program or the nature of the problems presented by their use.

This statement has been prepared by the Food Protection Committee to give some of the basic facts regarding the use of chemicals in foods, and the research and legal measures now being employed by industry and government to ensure protection of the public.

The constituents of foods are chemicals and may be classified as carbohydrates, fats, proteins, minerals, water and accessory factors, such as vitamins. The carbohydrates include various sugars, starches, dextrins, celluloses and gums. Most of these are oxidized in the body to release energy for muscular activity and other chemical reactions. The fats and oils supply energy and essential fatty acids and facilitate absorption of fat-soluble vitamins. The amino acids from proteins are used as building materials for muscles and other tissues or as a source of energy. The minerals, such as salts of calcium and phosphorus, are used in building skeletal structures and teeth. There are vitamins of various types present which regulate cell functions and are essential to normal metabolism, even though they are present in minute quantities. Such factors as the variety of crop, soil fertility or nutrition, intensity of sunlight during growth, disease, and methods of harvest and storage affect the chemical composition and nutritional quality of each product.

Each foodstuff consists of chemicals that are more or less characteristic of it. Milk, for example, contains water and solid matter, the latter consisting of a variable amount of butterfat, milk sugar (lactose), proteins (such as casein and lactalbumin), minerals (notably calcium and phosphorus) and other chemical constituents. These constituents of milk vary somewhat according to the breed, the individual cow, the period of lactation and the nature of the feed of the cow. Milk from Holstein cows is somewhat lower in fat and carotenoid pigments than that of either Jersey or Guernsey. Milks from different sources are quite generally blended or standardized to a definite level of butterfat.

Milk received at evaporating plants at different seasons and from different herds varies in stability to heat which affects the consistency of the finished product. Heat stability is dependent upon the balance in the milk of the natural mineral salts, particularly the proportions of calcium, phosphate and citrate. It is often necessary, therefore, to add one or the other of these chemicals in order to produce sufficient heat stability for a marketable product. This is a case of adding a constituent normal to milk to help standardize the product.

Standardization procedures comparable to those described for milk are carried out on various other foods, as in the blending of wheat varieties to secure a flour of uniform baking quality.

In addition to the natural variation in chemical composition of foodstuffs, chemicals may be incorporated during the growing or

during the storage and processing of the food. These chemicals may be described, for convenience, as "additives." When they are introduced to preserve or improve the quality of the product, they are known as intentional additives because they are purposely added to serve a specific need. Such materials as artificial coloring, synthetic flavors, sweeteners, vitamins for enriching bread, mold inhibitors, bactericides, antioxidants, emulsifiers and minerals are intentional additives. They are added to the food product in carefully controlled amounts during processing.

In addition to the intentional additives, other chemical additives may be present in foods when they are marketed. These are known as incidental additives. For example, pesticides required for the production of crops may remain in small quantities on foods. They can be avoided on or in foods to a large extent by proper use of materials during the growing and processing of the crop.

Why Are Intentional Chemical Additives Used?

Every chemical used in food production and processing should improve nutritional value, enhance quality or consumer acceptability, preserve food or make it more readily available to the public. Since there are many methods of improving food products and the efficiency of their production, only a few examples can be cited.

The enrichment of flour and bread with essential nutrients has improved the diet of the American people. The controlled addition of iodides to table salt to prevent goiter, and fluorides to drinking water to help prevent tooth decay, have long been advocated by responsible groups.

Uniform products are expected by the public, and chemicals are used to help attain this uniformity. Examples of such use of chemicals are the addition of naturally occurring materials, such as phosphates and citrates to evaporated milk, minute amounts of dyes to color margarine or to color butter to compensate for seasonal variations, and flavoring agents, both natural and synthetic, to control flavor intensity in many processed foods. Consumer dissatisfaction would result if, for example, brand-name products differed in flavor or color with every package.

Chemical additives are needed to preserve some foods, and their use has long been an accepted practice. Spicing and smoking of food products are typical examples of food preservation. Vinegar or sodium propionate is frequently used to prevent the molding of bread. Antioxidants may be added to fats and fatty foods to prevent rancidity.

Under no circumstances can preservatives be justified as a substitute for good sanitary practice. It is obvious, however, that the cost of food would be increased and its distribution would be handicapped by omitting them.

Necessity for the Use of Pesticides

Maintenance and improvement of the present nutritional status of the American public is contingent upon the continued production of an adequate food supply. Plant and animal pests rank among the foremost causes of food destruction, food deterioration and food contamination. Hence, the necessity of protecting growing crops and produce from serious attack by insects, plant diseases and other pests is recognized both from the standpoint of quantity and the quality of the food produced. In recent years, science has placed in the hands of the farmer, the food handler and the food processor many valuable chemicals to aid in the unending war against pests of all types.

The possibility that small quantities of pesticide residues may remain after harvest in the edible portion of treated crops has caused concern because some pesticides are known to be toxic to warm-blooded animals, and also because some crops need to be sprayed five to 12 times during the growing season to prevent damage by insects and crop diseases. Frequently, stored products such as the cereal grains must be further treated with fumigants to prevent infestation by insects and the growth of micro-organisms.

The application of pesticides is an expensive, disagreeable task that must be done at the time the farmer's other duties are heaviest. However, many crops would be destroyed if left unprotected. Crop failure occasionally might be escaped, but this risk cannot be taken in view of present intensive crop culture. Heavy investments in land, fertilizer, expensive farm machinery and labor must be protected from crop losses due to devastation by disease, insects and weeds. Use of pesticidal chemicals is an essential form of crop insurance. Although the pesticides cost about $200 million in 1949, and the quantity used in 1951 was materially larger, this is an unavoidable expense in modern agriculture.

Many things have contributed to the prevalence and destructiveness of insects, fungi, bacteria, nematodes and viruses during the past 50 years. Farmers are now forced to use the same fields over and over, since there is no more virgin prairie and forest soil to bring under cultivation. They can no longer move westward when fields become nonproductive, as their grandfathers did in the last century.

This gives the pests an ideal opportunity to find food plants in the immediate locality where they are established. After several generations they become so well adapted to the crop plants that they become extremely destructive.

Many farmers have found it difficult to use the long rotations of four, five or more years necessary to break up the life cycle of these pests. Another contributing factor is the present intensive cropping system, in which crops have been bred to such a state of uniformity that every plant in a field is almost equally susceptible or resistant to disease and insects. A few decades ago growers used open-pollinated, heterogenous varieties which varied in nearly every characteristic. Some plants might be attacked but others were sufficiently resistant so that affected crops were not, as a general rule, completely destroyed. Today, if a disease becomes established in a field it sweeps through all the plants like wildfire. By increasing the yield, uniformity, disease resistance and many other desirable characteristics of crops, substantial gains have been achieved, but at the price of greater hazard from pests.

In addition to our native pests, there have been introduced inadvertently several foreign ones. Some of these, such as the European corn borer and Mexican bean beetle, have become major factors in crop production. Quarantine barriers have not entirely excluded crop pests; many enter sooner or later on introduced plants, by wind-borne spores, or as flying adults.

Some enthusiasts have argued that plant diseases and insects could be controlled without using chemicals by the improvement of soils with organic matter. Agricultural scientists appreciate the value of organic matter in the soil but recognize that its presence is no guarantee against infestation. Diseases and insects were destroying plants long before man began cultivating crops and destroying soil organic matter.

Every effort is being made to control insects and diseases by good cultural practices. Plant pathologists and entomologists generally recommend that old crop refuse be plowed under or destroyed if pests live over the winter in it. Rotations with other crops are urged wherever possible not only to starve out pests, but to maintain balanced fertility and organic matter in the soil.

Intense effort is spent in locating geographical areas where pests are not established or fields where disease and insect pests are not likely to strike. By choice of suitable planting dates, many pests,

such as the Hessian fly on wheat, may be avoided almost entirely. Finally, appreciable sums are being expended in breeding crops for resistance to diseases and insects. Some astounding achievements have been accomplished by this research on pest-escaping tactics.

The development of resistant varieties is important, but has practical limitations. The resistant varieties may be perfect against one strain of a fungus, for example, but some parasites have as many as 200 strains. Experience has shown that a disease-resistant variety of oats or wheat will last only about 10 or 15 years before a new strain of the parasite develops and attacks the variety.

Beneficial Results from the Use of Pesticides

What would happen if chemicals were not used to control pests on crops? No one has risked such an experiment on a large scale. It is possible, however, to ascertain what is happening in spite of the best control measures and give some reliable opinions of what might be expected.

The corn borer was introduced into Massachusetts from Europe about 1917, and by 1927 had extended to Ohio. Within the past 15 years it spread into the corn belt, with losses of 30 to 50 per cent on many Illinois and Iowa farms. Corn production was seriously threatened before DDT was introduced, because losses increased from $5 million, in terms of 1941 prices, to $103 million in 1948 and $350 million in 1949 on the same basis. If chemical controls had not been developed in 1950, food for the livestock industry would have been reduced.

In Pennsylvania, yields of unsprayed apple trees declined over a six-year period so that they averaged only two bushels per tree, as compared to 11 bushels from sprayed trees next to them. A survey of sprayed and unsprayed orchards in that state showed that 82 per cent of the unsprayed fruit was destroyed by scab. Qualified authorities readily admit that this disease would eliminate apples as a crop in Pennsylvania if trees were not sprayed regularly. The average loss from this one disease alone in the United States is about 5.6 per cent, despite the control measures now being employed. Over the period from 1920 to 1939, the estimated monetary loss averaged about $10.5 million per year. The codling moth caused almost as much damage during the period from 1944 to 1948. Prior to the discovery of DDT, the loss averaged about $50 million a year (15 per cent of the crop).

An excellent example of the destruction that can result from the unchecked attack by a pest occurred on tomatoes in 1946. Late blight,

a fungus disease, became established in Florida early in the season and progressed northward. Less than 10 per cent of the tomato crop was being sprayed at that time, so that there was a good opportunity to study an uninhibited epidemic under modern conditions. The losses, then estimated at $40 million, exceeded 50 per cent in ten of the states along the Atlantic seaboard. Canning factories closed down and the price of market tomatoes increased ten- to 20- fold. Farmers were so discouraged that they discontinued tomato culture. In Pennsylvania, for example, the tomato plantings within two years declined from 34.2 to 19.4 thousand acres. After spray measures were perfected with resultant improvement in yield, the acreage increased. It is doubtful whether tomato culture would have been fully restored in decades without this protection afforded by fungicides.

Some of the other benefits to consumers from use of pesticides are even more impressive. Dairy cattle produced 15 to 20 per cent more milk where spray programs to control flies were introduced after the new organic insecticides were discovered. Treated beef cattle in Kansas averaged 50 pounds more gain per animal than did unprotected cattle when all the animals had the same food supply. These benefits were conservatively estimated at $100 million annually.

The control of grasshoppers in Montana and Wyoming in one year saved enough pasture grass to produce about 11 million pounds of beef. In 1938 almost nine million acres of pasture and crop lands, with crops valued at $68 million, were treated. In 1949, treatments saved about $72 million, even though another $27 million damage was recorded. Each dollar invested in control yielded a $55 gain in produce during 1949.

These random examples give some indication of how severely a single insect or disease may affect agricultural production. It must be remembered that there are thousands of these pests, each attacking crops and livestock in varying degrees. The battle lines between them and man are well drawn. Pests must be controlled or the food supply of the nation will decrease markedly in quantity and quality. These inescapable facts make it plain that chemicals are destined to continue as much a part of farming as the tractor.

A clear distinction should be made between hazards which may exist, or result from accident, during manufacture or during the use or application of large quantities of pesticides to protect crops or animals from the ravages of pests, and the hazards which may result if more than minimal quantities of these chemicals remain in foods. Food

hazards should not be confused with hazards due to accident during manufacture, use or application.

Also, a careful distinction must be made between hazard and toxicity. Toxicity is the capacity of a substance to produce injury; hazard is the probability that injury will result from the use of the substance in the quantity and in the manner proposed. An estimate of the hazard in relation to any substance must be based upon knowledge of the toxicity and of the details of its use.

There need be no hazards involved in the use of chemical additives in foods, provided adequate scientific research programs are carried out prior to the use of an additive. The fact that a chemical is toxic does not mean *per se* that its proper use as an additive will entail a hazard to man.

Practical and effective, though not perfect, scientific techniques have been worked out to determine the toxicity of chemicals to laboratory animals. Taking into consideration the toxicity of the chemical, the amount proposed for addition to food and the variety and types of food to which it is proposed to be added, it is possible to reach an expert judgment of the hazard involved. With this information available, no reputable manufacturer would add any chemical to food when a hazard to the public health is involved. Legal measures are designed to protect the public from any use of chemical additives without these adequate safeguards. A select committee of the House of Representatives is at present investigating the adequacy of existing legislation to accomplish this purpose.

Questions of hazards posed by chemical additives in foods require objective unbiased scientific study, with due consideration of many types of possible advantages and disadvantages which may accompany the use of the proposed additive. It is fundamental, however, that decisions regarding foods should aid in making possible an adequate supply of wholesome foods with good consumer acceptability. A wholesome food product must, among other qualities, supply at least the nutritional values which are traditionally associated with the food, and it must be safe for continuous use in the diet under a variety of patterns of consumption which are to be expected to occur during the course of its use. Decisions emerging from such a variety of considerations must involve judgments made through understanding and interpretation of critically designed scientific studies. The considerations are so varied as to demand group study and mature, conservative judgment.

Experimental studies of the physiological, pharmacological and bio-chemical behavior of a proposed additive, made in various species of laboratory animals and in limited numbers of humans, can reduce to a very low degree the uncertainty of its safety. The extent of such studies of a particular additive in food varies with several factors which determine the amount and form likely to be consumed by the human. A group of such considerations have been proposed recently by the Food Protection Committee.

An intentional chemical additive should not be used in a food until its safety for a given food use has been established beyond reasonable doubt, as judged by competent experts. Similarly, the safety of incidental additives must be established in terms of their occurrence in food products as marketed. While the ultimate test of complete safety is the alert observation and intelligent scrutiny of the effects of the use of a substance in foods, a new additive should not be used until the best judgment based upon studies on animals and, where possible, on man indicates that deleterious effects will not result.

What Precautions Are Being Taken?

General Procedures.—During the past several years, there has been considerable discussion of the possibility that hazards might accompany the use of chemical additives in the production and processing of foods. Although there has been no justification for any of the exaggerated viewpoints that have been widely circulated, it is true that so many new chemicals have been introduced in the past ten years, and still others are in immediate prospect, that it is well to examine the existing situation.

Contrary to some ideas that have been circulated, reliable food processors have not reduced the nutritional quality of our foods or created inferior products through the use of chemical additives. Actually, the quality and sanitary characteristics of our foods have been improving. Likewise, there is no evidence that consumption of foods resulting from the use of the new materials in crop production or in the production and processing of foods has created mysterious disease epidemics or endangered the health of people. It is to the credit of industrial concerns and law-enforcing agencies that they have been able to make so much progress without jeopardizing the health of the public.

The first evaluation of toxicity of chemicals is usually made by the companies which create them. This is necessary to protect the employees who must handle the chemicals in the factory and research

laboratory and, later, to protect the food and to maintain the good will and confidence of consumers. The reliable industrial concern starts toxicity measurements as soon as a new material shows promise of beneficial use. The first experiments are usually made in their own laboratories or under contract with a private toxicological laboratory staffed by competent toxicologists. In addition to these direct services, many concerns have also established fellowships and grants-in-aid with medical colleges, universities and hospitals where they can secure disinterested advice and find competent pharmacologists and toxicologists to direct the research.

Most pesticide manufacturers usually complete acute toxicity measurements on at least one animal species by the time they have completed laboratory studies on the usefulness of chemicals under consideration. More extensive experiments, including the determination of chronic toxicity, may be made while the material is being tried in experimental field plots. Pesticidal chemicals rarely prove their value in field use in less than five years of experimentation. Government agencies are cooperating with industry in developing a program whereby the necessary field experiments can be conducted on a limited commercial scale while toxicological research is still in progress.

Many food processors also have established their own laboratories and have exercised precautions in using new materials. Some of the progress in detecting residues of pesticides and in developing methods for removing traces of chemicals by washing has come from these laboratories. They, too, have sponsored extensive research in colleges and universities, particularly in the field of nutrition.

Although the reliable chemical manufacturers and food processors have established these procedures, there is room for honest differences of opinion in interpreting the hazards involved. Wide differences of opinion can usually be resolved by further study and consultation with the appropriate government agencies.

Functions of Federal Government Regulatory Agencies.—Four federal agencies are responsible for the protection of the public. They function by the administration of different laws and by conducting their own research.

The United States Public Health Service is responsible for public health in its broadest aspects. Investigations are made into the use of chemicals to control diseases and insects affecting man, the effect of chemicals on men associated with the manufacture of chemicals, the effect on spray operators and the effect of ingested chemicals

on man. In addition to using small animals for research, the service also performs epidemiological field studies and carries out clinical investigations on human subjects whenever necessary. The Public Health Service also acts in an advisory capacity to state and local health departments in devising and enforcing ordinances regulating the handling of food and milk.

The Meat Inspection Service of the United States Department of Agriculture controls the use of certain chemical additives in meat and meat-food products under authority of the Meat Inspection Act of 1907. The latter act provides for special inspectors in any establishment processing meat foods for interstate or foreign commerce. Under this act, no chemical additives may be used in meat or meat products without approval of the service.

The Insecticide Division of the United States Department of Agriculture is responsible for the registration of all pesticides under the Insecticide, Fungicide, and Rodenticide Act of 1947. Before any pesticide can be sold interstate, data must be submitted on its ability to control pests, its safety for use by spray operators and on crops, its effects on quality and safety of food, and the potential damage to other forms of life and to soil. The division does not conduct research of this type, but depends on scientists in the Agricultural Research Administration for advice on usefulness, and on the toxicologists in the Public Health Service and in the Food and Drug Administration for opinions on safety for the proposed use.

The Administrator of the Federal Security Agency is charged with the responsibility of enforcing the Food, Drug, and Cosmetic Act of 1938. He has the power to prevent shipment in interstate commerce of any food adulterated by a poisonous or deleterious ingredient. The Administrator is also responsible for the establishment of standards of identity for food products and for the promulgation of tolerances for chemical additives where these are required in processing. The Food and Drug Administration maintains elaborate toxicology laboratories.

The Food, Drug, and Cosmetic Act directed the Federal Security Administrator to establish a safe residue-tolerance level for each chemical shown to be a poisonous material, but necessary to the production of food. Exhaustive hearings on pesticides were held in 1950, and formal tolerances are expected in the near future. Informal tolerances for lead and arsenic, fluorine, and DDT have been in use for some time. Although many samples of fruits and vegetables have been examined, there have been no seizures by the Food and Drug Admin-

istration for exceeding the tolerance on DDT, and only three seizures in the past three years for the presence of lead arsenate in excess of the informal limit. Prior to 1947, there were a larger number of seizures for exceeding lead and arsenic informal residue limits because such heavy treatments were required before DDT was introduced to control the codling moth.

New intentional chemical additives may be introduced into foods by either of two procedures. Some foods have established standards of identity promulgated by the Administrator of the Federal Security Agency only after review of all existing data. Anyone wishing to substitute a material for an ingredient named in the standard or to add a new substance must petition for a hearing. Many foods do not have established standards of identity, so that the food processor must carry the full responsibility for adding any new chemical and must observe the provisions of the 1938 Act that prohibit the addition of poisonous or deleterious ingredients. Reliable processors consult with the Food and Drug Administration, and conduct such experiments as may be suggested and additional research which they regard as essential.

The adequacy of existing legislation to safeguard the public health in relation to the use of chemicals in foods has recently been under consideration by a House of Representatives select committee. The United States Commissioner of Foods and Drugs has testified before this committee that existing legislation is not adequate, and additional legislation has been proposed. The opposite viewpoint has also been presented to the committee.

In addition to the federal laws, 40 states have laws regulating the use and sale of chemicals. These laws are administered either through the departments of public health or agriculture in the various states. Some of these laws are modeled on a uniform pattern, while others vary in important respects. A concerted effort has been made to encourage the standardization of these laws so that the movement of chemicals in interstate commerce would be facilitated.

• *Recent Amendment of Antibiotic Regulations* •

Regulations governing certification of antibiotic and antibiotic-containing drugs have been amended to provide for certification of two new preparations, penicillin-streptomycin dental cones and penicillin-dihydrostreptomycin dental cones.—CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 1550 (December 29, 1951).

AN EXPERIMENT IN

Interprofessional Education

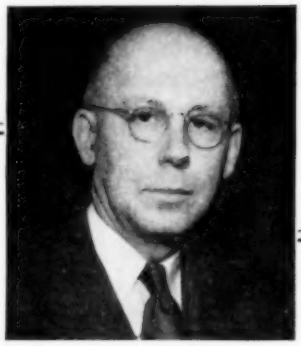
The Author, Dean and Professor of Law, School of Law, University of Pittsburgh, Describes an Experiment Which Has Considerable Significance as a Pioneer Educational Project in the Food and Drug Field

ONE OF THE AIMS of the law school faculty of the University of Pittsburgh is to supplement traditional legal education with training in the solution of practical problems involving various fields of the law.[1] Another is to bring together law students and representatives of other disciplines for the mutual advantage of the groups concerned. In this, the school has enjoyed the wholehearted cooperation of the various branches of the university.

During the past summer an experiment has been conducted which, we believe, has considerable significance as a pioneer educational project in the food and drug field. Organized as an exercise in administrative rule-making, the problem took the form of a hearing on a proposal to amend the standard of identity for oleomargarine. It has been suggested that readers of the JOURNAL might be interested in a description of the project and an evaluation of its significance.

It may be said at the outset that the University of Pittsburgh is particularly strong in the field of food chemistry. Thus, when H. E. Longenecker, Dean of the Graduate School and of Research in the Social Sciences, was asked to give his advice regarding a program in which graduate students in science and law students might work together, it was quite natural that a food problem should be considered. Originally it was thought that a hearing in connection with adding emulsifiers to bread might be appropriate, but this was soon discarded as being too cumbersome and complicated to handle in a brief period of time. Finally, agreement was reached that a hearing

[1] See Taintor, "Required Summer Term and 'Problem' Course," 2 *Journal of Legal Education* 347 (1950).



By CHARLES B. NUTTING

on a proposal to amend the standard identity for oleomargarine in certain respects would be feasible.

Several circumstances brought about this decision. Dr. B. F. Daubert, at that time Research Administrator in Chemistry at the university, had done extensive work in the field and at once offered his enthusiastic cooperation. Ashley Sellers, General Counsel of the National Association of Margarine Manufacturers, by virtue of many years of association with the member of the law school faculty in charge of the project, had learned to regard with equanimity demands made on him in the name of education. Vincent A. Kleinfeld, also an acquaintance of the instructor in charge, cheerfully allowed his brains to be picked and was instrumental in furnishing valuable background information. All of these factors made it seem practical to continue with the undertaking.

The next step was to secure the necessary experts on the technical side. Here Dr. Daubert proved invaluable, since he was able to induce eight graduate students working in food chemistry to volunteer their services.[2] At a meeting with these students it was pointed out that the proposed hearing would give them an opportunity to act as expert witnesses or as government advisors, and that this would constitute valuable training, since they would undoubtedly act in such capacities during their professional careers. The students expressed great interest in the project, and subsequent experience showed the wisdom of choosing them.

[2] Messrs. P. W. O'Connell, L. J. Swicklik, J. Taber, S. C. Caruso, C. E. Bole, J. B. Harrison, H. Pilat and L. Silbert.

Discussion then followed with Dr. Daubert regarding the scope of the proposal upon which the hearing would be held. Obviously, it was desirable to have a real contest, and for this reason it was necessary to select for inclusion in the proposal ingredients about which there was a legitimate controversy. Finally it was determined to go to hearing with respect to certain ingredients.[3]

Student Participation

In the meantime, eight law students who had completed two years of study had either volunteered or had been dragooned into participating in the problem. They were divided into teams or "firms" of four persons each, one representing a mythical manufacturing company[4] and the other comprising the staff of the office of the general counsel of a hypothetical food and drug administration.[5] The instructor in charge was simultaneously the president of the company and the administrator of the regulatory agency. In the former capacity, he informed his lawyers that he wished to introduce the ingredients previously mentioned into the oleomargarine and inquired what must be done to make it safe for him to do so. As administrator, he notified his staff that there was a movement on foot to include the ingredients and asked what could be done to prevent it.

The industry firm first proposed that permission be secured to include the ingredients on an experimental basis, pursuant to certain provisions of the regulations.[6] An application for such permission was denied. Then the firm prepared an application for hearing which was granted and a notice was filed for "publication in the *Federal Register*." The instructor, in his capacity as administrator, designated himself under the name of John Doe as hearing examiner.

Interprofessional Cooperation

Preparation for the hearing then began. Due to the shortness of the time involved, it was necessary to waive the usual requirements in this respect and the hearing actually commenced about two weeks

[3] Tartaric acid, in an amount not to exceed .05 per cent of the total weight of the finished product; the Methyl-, Ethyl-, Propyl-, and Butyl-Esters of Parahydroxy Benzoic Acid, in an amount not to exceed .1 per cent of the total weight of the finished product; fatty acid derivatives of polyoxyethylene glycol, in an amount not to exceed .2 per cent of the total weight of the finished product; Vitamin C, in an amount not to exceed .005 per cent of the total weight of the finished product; and Tocopherol, in an amount not to exceed .005 per cent of the total weight of the finished product. These were to be listed as optional added ingredients in the amended standard.

[4] Mrs. Roslyn Litman, Messrs. E. J. Goldfarb, L. A. Zehner and J. F. O'Malley.

[5] Mrs. Marjorie Young, Messrs. R. I. Kingsley, J. D. Duncan and W. G. Kerr.

[6] 21 CFR, Sec. 3.12 (1950 Supp.).

after the notice was issued. Each firm was referred to its respective group of experts, and there ensued long hours of conferences in which the scientists attempted to explain the scientific facts to the lawyers and the latter tried to acquaint the former with the legal and procedural requirements involved. So intensive was the preparation that the wife of one of the chemists was heard to complain that the lawyers were interfering unduly with her home life.

On July 11, 1951, the hearing was opened. It continued for the better part of three days. Since financial resources to hire a reporter were lacking, the record was made through the use of a wire recorder borrowed from the department of speech. It might be added parenthetically that the use of the recorder proved valuable, since by playbacks the students were able to hear and criticize their own techniques much more effectively than would have been the case had they been forced to rely on a stenographic transcript.

Question-and-Answer Presentation

In order to give everyone a fair chance to participate, each of the "industry" counsel presented the testimony of one expert. It was deemed best for the purposes of the problem to have the testimony presented by questions and answers rather than by the reading of a prepared statement. At the conclusion of the testimony of each witness, "government" counsel cross-examined with the aid of a graduate chemist who had prepared himself to discover weaknesses in the case as presented through his opposite number. As in the case of the direct examination, each "government" lawyer was responsible for examining one witness. Statistical and other information was presented through the use of exhibits prepared for the purpose and, in some instances, by requesting the examiner to take official notice of matters of public record.

As far as possible, the hearing was conducted in a realistic manner. The examiner, having some years previously served briefly as a hearing officer for a federal agency, endeavored to give an official aspect to the proceeding, although at times the pedagogue triumphed over the bureaucrat. Objections to questions and the production of documentary evidence were heard and disposed of. The qualifications of the expert witnesses were made a subject of inquiry. Rulings on motions and objections were argued vigorously, and not entirely with-

out acrimony. The case as a whole was earnestly contested throughout, and the competitive spirit was obviously present not only among counsel, but among the scientific experts as well.

After the hearing, briefs, arguments and proposed findings were filed by the "industry" group, and at the request of the examiner were also submitted by the "government." These documents were considered in the light of the evidence, and a proposed order was issued.[7] Further post-hearing procedure was omitted because of lack of time.

Experiment Evaluated

In assessing the value of the problem, several conclusions seem to be warranted. It is clear that the primary objective was successfully attained. The law students showed a remarkable ability to assimilate a body of highly technical scientific information and to present it in an orderly manner. The scientists, in addition to exhibiting patience and a cooperative spirit of the highest order, gained an understanding of and respect for the legal incidents of an administrative proceeding. In addition, both groups gained confidence in their ability to explore new fields and to master novel situations without formal instruction in the subject matter.

Perhaps more fundamental is the fact that the administrative proceeding, to borrow a term from the chemists, served as an effective "emulsifier" in combining law and science, two ingredients of modern life which are popularly supposed never to mix. All of the participants, faculty as well as students, completed the problem with increased respect for one another and with an enhanced appreciation of the contributions which the respective disciplines can make in the cooperative solution of social problems. We hope that this is the first of numerous instances in which interprofessional cooperation of this type can be carried on in our institution.[8] **[The End]**

[7] In substance, the order permitted the addition of the Parahydroxy Benzoic Acid Esters and of Tocopherol, but denied the application for the addition of the other ingredients listed in footnote 3, above.

[8] A different approach to the problem in the field of organized research has been made in connection with the preparation of public health legislation. See Stahl, "Public Health Law Reform in Pennsylvania," 6 FOOD DRUG COSMETIC LAW JOURNAL 454 (1951).

THE FOOD LAW INSTITUTE PAYS

A Tribute to

Dr. PAUL B. DUNBAR,
Administrator (Retired),
Food and Drug Administration

On November 14, 1951, The Food Law Institute Held a Ceremony in Honor of Dr. Dunbar. Below Is Dr. Dunbar's Speech in Accepting the Institute's Award of Distinction, Followed by Mr. C. W. Crawford's Remarks on That Occasion

THE FOOD LAW INSTITUTE has been most generous in presenting this award. I accept it gratefully but not in a wholly personal way. It must be regarded as a tribute to the men and women who have labored constructively for more than a generation to make the Food and Drug Administration an outstandingly useful governmental organization. Many of them early recognized in food law-enforcement work an opportunity for a challenging type of public service and decided to make it a career. Few of them have regretted this decision.

The Food Law Institute was created by the food industry. It is appropriate, therefore, to make some observations about that industry. I think I can survey the food situation in this country in a detached way, since I am no longer in regulatory work and have never had commercial connections. As a consumer, I know that there are available to me the most varied, the most wholesome, the purest and most honestly labeled foods of any nation. I know that the sanitary controls maintained in our food plants are the highest in our history and that our manufactured foods are prepared with a care that equals and often exceeds that exercised by the careful housewife in her own kitchen. When I sit down at the table I am assured of a greater margin of safety than is enjoyed in any other country on earth.

We owe this happy situation to three things. First, we have a splendid national law, the Federal Food, Drug, and Cosmetic Act of

Dr. Dunbar Retired as Food and Drug Administrator on May 31, 1951, After Serving in That Capacity Since 1944

1938. It was evolved out of a half century of experience and, as a living and dynamic instrument of public protection, has been and will be kept up to date by appropriate amendments. Second, we have a firm and effective enforcement of this law. Third, we have a national food industry that has the will and the know-how to control factory practices in a manner calculated to manufacture products worthy of consumer acceptance.

As a citizen, I am proud to live in a country that has the legislative foresight to enact such a law and provide for its effective enforcement. I am glad that we have a food industry that recognizes its obligations, both legal and moral, to supply the consumer with sound and honest products.

Not only is that industry, through its own research, continually developing new techniques for the production of better products, but it has displayed an unusual degree of practical idealism by endowing the Nutrition Foundation and the Food Law Institute. One is committed to the improvement of our standards of living by fundamental research in nutrition, the other to the study and teaching of our basic law of food. Both are monuments to the far-sighted generosity of the food industry intended to promote the national welfare. In its first decade, the Nutrition Foundation has made an impressive record of achievement. In two short years the Food Law Institute has shown itself to be an active and virile organization. As the second annual report of the institute has so well said, the Nutrition Foundation and the Food Law Institute are pioneer organizations playing a new role in food progress; together they constitute a long-range program of fundamental public service—a program of enlightened industrial statesmanship.

While I know these things as an informed consumer, I am fully aware of reports now being circulated that our American food supply

is debased by over-refinement and dangerously contaminated with chemicals. Careful food processors, as well as consumers, have every reason to be concerned about these reports. They stem in large measure from fears that dangerous insecticidal residues may remain in foods ready for the table, that soil impoverishment is resulting in food crops of lowered nutritional value, that manufacturing processes are removing vitally needed food elements, and that chemical additives are being employed to cover up deficiencies and to give a fictitious appearance of quality. These fears have their origin in a misinterpretation of scientific evidence and an overemphasis of hazards which never existed or have been largely eliminated or are due to the sins of the careless few.

There is no point in evading the issue. What are the facts? If we are to feed America and much of the rest of the world we must fight crop-destroying insects. Chemical sprays are the only presently effective means of waging this battle. There is today a clear-cut understanding by all who are engaged in the production and processing of foods that insecticides must be used with such precautions that harmful residues will not remain on the foods when ready for consumption. Such precautions are taken. Legal action can be and is taken under the Food, Drug, and Cosmetic Act in the occasional instances where excessive residues are found.

As to food debasement through soil depletion, soil scientists and nutritionists point out that Americans enjoy the most widely varied diet of any nation. Our markets are stocked with provisions from every section of the land. This variety helps to assure the normal family an ample supply of all the essential food elements. The experts concede that some soils will not produce profitably large crops, but the evidence indicates that the small crops produced there do not lack nutritional quality. The only soil deficiency definitely shown to be related to human food needs is that due to iodine shortage. The need for iodine has been met, where soil conditions require it, by the use in the diet of iodized salt. Since we seldom subsist on the products of a restricted area, the hazards of nutritional deficiency through soil depletion are extremely remote.

Charges of over-refinement and chemical treatment have been especially directed against flour and bread. When our colonial ancestors carried a sack of grain to the local mill, they could be sure of getting back a ground meal containing everything the sack originally contained, including such incidental debris as had been deposited

by rats, mice and insects. They could also be sure that, unless the meal was used promptly, it would become inedible as the oil of the wheat germ grew rancid.

Dr. Anton J. Carlson, the world-famous physiologist, has testified that as far back as the Roman Empire, white bread on the table was a mark of social distinction. Be that as it may, as our country progressed, consumer demand for whiter flour and whiter bread increased. It is true that the extra refinement removed some highly desirable nutritive elements, along with the quick-spoiling wheat germ. The general adoption of the flour-enrichment program recommended by the National Research Council has provided for the addition to flour and bread of the needful vitamins and minerals. Enriched flour today is remarkably clean and nutritionally sound.

As to chemicals in foods, it is, of course, a fallacy to condemn all chemical additions. Many chemicals, like the flour-enriching agents, are recognized by nutritionists and medical experts as useful, valuable and even essential. Two tests must be applied to any proposed chemical addition. First, is it completely harmless? Second, does it serve a truly useful purpose from the consumer standpoint? The specialists in the Food and Drug Administration have formulated principles for determining harmlessness. Food processors today are routinely carrying out the recommended tests and submitting their results to the Food and Drug Administration for evaluation. It is rare indeed to find a manufacturer who persists in employing a chemical against the advice of the specialists.

The Food and Drug Administration's Annual Report for 1950 states that of more than 77,000 firms dealing in foods, drugs and cosmetics subject to the federal law, less than 2 per cent were implicated that year in seizures or criminal actions. It is safe to assume that this percentage holds good for the food industry. But the example set by the scrupulous 98 per cent is not enough to offset the damage done by the reckless or careless few. As long as there are any who take chances with the consumer's welfare, the entire industry is exposed to the kind of adverse publicity that is now so disturbing.

The Food and Drug Administration can be relied upon to take all possible legal steps to deal with the offending 2 per cent. But the industry itself can do something to maintain and fortify public confidence. Through appropriate publicity, it should tell consumers the facts about the precautions now so universally employed in American food plants to insure purity and quality. One way to accomplish this

would be to expand the facilities of the Food Law Institute. Its educational program has been well and logically begun in graduate law schools. The second annual report of the institute has pointed out a field for educational advancement in schools of agriculture, nutrition, public health and home economics. Our future teachers should be given the true facts about the American food industry and the integrity of our food supply.

Twenty-five years ago, Dr. Charles A. Brown, then Chief of the Bureau of Chemistry, noted in his Annual Report for 1926 [1] the gradual transfer of the manufacture of food from the home to the factory. He stated:

> Perhaps the greatest benefit that has come to the food industry through efficient food law enforcement has been the increased confidence of consumers in the purity and wholesomeness of the food supply of the Nation.

If that confidence existed a quarter of a century ago, it should exist today in even greater degree under the far more adequate Food, Drug, and Cosmetic Act of 1938. That confidence will be fortified if consumers are given the information they are entitled to about the purity and wholesomeness of their foods. **[The End]**

FOOD LAW INSTITUTE AWARD:

A Tribute Address

By C. W. CRAWFORD

DR. DUNBAR'S CAREER of 44 years in the Food and Drug Administration spanned an era of vast significance in the economic and social life of this country. It was an era of change in every phase of human interest. Those changes brought about in our food and

[1] *Federal Food, Drug and Cosmetic Law, Administrative Reports, 1907-1949* (Food Law Institute Series), p. 663.

Mr. Crawford Is Commissioner of Food and Drugs, Federal Security Agency

drug supplies were more sweeping than had occurred throughout all previous history.

His career began at the time when every community depended largely on its locally grown food supplies. The art of food preservation was not advanced, and our diets were adapted in a large measure to seasonal production. The items available in the local grocery store, most of which were of the old cracker-barrel type, were comparatively few. Sanitation as we know it today was practically nonexistent.

For our drugs we depended largely on what the pharmacist compounded in the local drugstore, or we might try some of the cure-alls so common to that day. At best, we could get only some palliation for most of our ailments.

It was a far cry indeed from the bounteous supplies we have today of a great variety of nutritious foods, in season and out, and from the highly effective and life-saving drugs that are produced in our modern factories.

Insight into Regulation Problem

The country is fortunate indeed that Dunbar chose a career in the field to which he devoted his life. He came into the service in 1907, just after the original food and drugs law had been enacted. This legislation came from a recognition that in a nation which was becoming rapidly industrialized, and which was dedicated to free enterprise, the doctrine of *caveat emptor* should not apply in the sale of commodities so vitally important as foods and drugs. Curbs were essential for those, in the industries, who abused their freedom—who did not accept the responsibilities that freedom imposes. Dunbar saw clearly that the real problem was to exercise such restraints as were essential to insure honesty and fair dealing in the interest of

consumers, without unnecessary restrictions on freedom of development and growth. His whole career has been guided by this fundamental view.

To undertake even to list his accomplishments would take far more time than this occasion affords. That they covered a wide area is well known. He made contributions in science, administration and organization. He exercised a profound influence in his field on legislation and public relations.

He was always impressed with the urge, shared by the great majority of the industries, continually to improve their products. New products and new methods of preservation and distribution that would give the consumer a wider choice and better quality always had his sympathetic approval. He stands in admiration of the industries which were responsible for the differences between today's groceries and drugstores and those he knew at the beginning of his career.

Foresighted Endorsement of FLI

His belief in fair and effective food and drug legislation and enforcement has been a continuing passion. He enthusiastically endorsed the proposal for the Food Law Institute when it was first advanced by your president. He saw in it a potent aid to sound development of the law and its administration. He saw that the wider dissemination of knowledge of the philosophy underlying the law, and the better understanding of it that would come from the program of the institute, would inevitably lead to even better and more nutritious foods and safer and more effective drugs for the American public. I am sure he regards the establishment and effective functioning of this institute, which occurred almost simultaneously with the termination of his official career, as a landmark in the evolution of a basic idea to which he devoted his life.

Mr. President, I am glad to join with you and with the Food Law Institute in tribute to the outstanding achievements of the man we honor today. **[The End]**

The Nutrilite Consent Decree

The Author, a Member of the California Bar, Analyzes the Consent Decree Which Was Filed in The *Nutrilite* Case—One of the Most Bitterly Fought Litigation Wars in the History of the Federal Food, Drug, and Cosmetic Act

IN the early part of March, 1951, representatives of the Federal Food and Drug Administration sat at a conference table in the Federal Building in Los Angeles to discuss with the representatives of Nutrilite Products, Inc., and Mytinger & Casselberry, Inc., manufacturers and distributors, respectively, of Nutrilite Food Supplement, the possibilities of arriving at an amicable and mutually satisfactory settlement of the extended *Nutrilite* litigation. (For brevity, the manufacturer and distributor will be hereinafter referred to jointly as Nutrilite.) Criminal action for misbranding based upon previously discontinued literature had been filed in September, 1948, and was still awaiting trial. Ten libel actions which had been filed in various parts of the country from Seattle to St. Petersburg, Florida, had been consolidated in San Francisco, as a result of hotly contested removal proceedings which were heard in Newark, New Jersey, and were awaiting trial. An injunction action, brought under Section 302 (a) of the Federal Food, Drug, and Cosmetic Act, which had been filed in the District Court in Los Angeles in October, 1949, was also ready for trial.

Another suit, one which had been filed by Nutrilite against the Federal Security Administrator, the top officials of the Federal Food and Drug Administration, and the Attorney General of the United States in December, 1948, had already been terminated. This law suit had been brought on the ground that the provisions of Section 304 of the act, which permitted multiple seizures of an admittedly harmless product when the Federal Security Administrator believed its advertising to be misleading, was unconstitutional because the

By LESTER L. LEV

Administrator could so rule without giving the party a hearing. The second ground for the injunction was that the food and drug officials had deprived Nutrilite of its property without due process by reason of their arbitrary, capricious and unlawful actions in carrying out their official duties, and that the literature which was the basis of the seizures was not violative of any law. After hearing evidence for almost two weeks, a three-judge court sitting in Washington, D. C., issued a permanent injunction enjoining any further seizures of Nutrilite. The trial court found for Nutrilite on both issues [1] but the United States Supreme Court reversed on the ground that the provisions of Section 304 permitting multiple seizures without a hearing did not violate the Constitution. As to the second ground, that is, that the food and drug officers were aware of the fact that the use of most fully, the higher court held that the trial court had no jurisdiction to inquire into such matters and that the decision of the Federal Security Administrator in authorizing multiple seizures was unreviewable.[2]

At the Los Angeles meeting, both sides realized that in the absence of settlement, months would be consumed in trial and, possibly, years would pass before all the cases would be finally disposed of on appeal. All of the litigation arose out of FDA's claim that the literature used by the distributor, Mytinger & Casselberry, Inc., in the sale of Nutrilite Food Supplement was false and misleading. The food and drug officers were aware of the fact that the use of most

[1] *Mytinger & Casselberry, Inc. v. Ewing*, 87 F. Supp. 650.

[2] *Ewing v. Mytinger & Casselberry, Inc.*, 339 U. S. 594.

of the printed material of which they had complained had long previously been discontinued by Mytinger & Casselberry, Inc., and that much of the balance had never been used or authorized by it, although the food and drug representatives had found some of such material in the hands of distributors in various places throughout the country. It seemed at the outset that inasmuch as Mytinger & Casselberry, Inc. was at that time utilizing only a few pieces of literature, the task of arriving at a settlement should not be too difficult.

Viewing the history of settlement of negoiations in retrospect, it was probably on February 12, 1951, that the groundwork was laid for settlement. On that date, Federal Security Administrator Oscar R. Ewing gave his deposition in the pending injunction case. One of the statements questioned by FDA was the claim by Mytinger & Casselberry, Inc., that there were nutritional deficiencies in the average American diet. FDA had consistently taken the position that such a statement was not supported by facts and was merely the figment of the distributor's imagination. However, the distributor had relied upon a number of outstanding authorities and believed that the average American diet was in fact deficient. One of the authorities relied upon was Mr. Ewing's 1948 report to the President of the United States entitled *The Nation's Health, A 10-Year Program.* According to the report itself, it had been compiled with the aid of 800 experts. This report had been used by Mr. Ewing to bolster his well-known campaign in favor of what many persons have termed "socialized medicine." During the taking of the deposition, Mr. Rhyne, Washington counsel for the Nutrilite group, interrogated Mr. Ewing with respect to the 1948 report. The following questions and answers were asked and given, excerpts from the report being read by counsel:

Q. "Dietary deficiency diseases in severe form—scurvy, rickets, and pellagra—are not so common among children as a decade or two ago. But they still exist, particularly among children of low-income families. Many more children suffer from general malnutrition, which causes them to grow at less than the normal rate and have less than average resistence to infections.

"In some parts of the country, a recent study showed, as many as 72 per cent of pregnant women and 85 per cent of children of early school age were suffering from secondary anemia."

Is that an accurate statement to the best of your information and belief?

A. Yes.

Q. Directing your attention now, Mr. Ewing, to page 25 under the heading "Nutrition", the statement is made:

"Despite our progress in acquiring knowledge about nutrition, people are still dying from the effects of nutritional deficiency. The widespread effect of inadequate diets is evident in poor resistance to disease."

That, Mr. Ewing, is a statement based upon this preparation that you have described and is true and accurate to the best of your information?

A. Yes, sir.

Q. Mr. Ewing, you have thoroughly explained the preparation of this report, and let me ask you: Do you believe that this report is not false or misleading in any particular?

A. Not to my knowledge.

Q. And, Mr. Ewing, do you believe that the statements contained in this report express the consensus of medical opinion as developed in the way you explained it?

Mr. Kleinfeld: May I explain for the record, though of course there is no judge here to rule on this, and since Mr. Ewing is not a doctor, he is not qualified to answer these questions, and of course at the trial we will object to these questions, because Mr. Ewing has not been qualified as a doctor or scientist of any sort, not qualified, but since there is no judge here to rule on the question, if you want to ask it, go ahead.

By Mr. Rhyne:

Q. Do you want the question repeated?

A. No, I can answer this question—that the materials, that every statement that is in there represented the best judgment of the experts who worked with us in its preparation.

Q. And those experts were certainly the top qualified people obtainable at that time?

A. Well, I don't know that you could phrase it quite that strong.

Q. They were qualified to express their opinions, were they not?

A. We thought so, but whether they were the best, somebody that is left out might have disagreed violently with that conclusion.

I will say that in every instance that, as far as we knew, we thought they were qualified to express the opinions.

Q. Do you still think that?

A. I have had no reason to change.

It was apparent that neither Mr. Ewing nor the FDA relished the thought that at the trial the Nutrilite group would be sure to reveal the fact that, although it relied upon the Federal Security Administrator's report to the President of the United States, that the FDA had consistently taken a position directly contrary to the report of its own chief. The Administrator would be faced with the spectacle of his own subordinates testifying under oath that his report to the President was false and misleading. The embarrassment which was bound to follow could be avoided only if the litigation were settled before trial.

In any event, it was but a short time after Mr. Ewing's deposition was completed that it was agreed to attempt to work out a settlement.

The first day of the meeting consisted of general discussions and exchange of tentative proposals for settlement. Each successive day

brought its redrafts. It was indicated almost immediately that the framework of the settlement would encompass the filing of a consent decree in the injunction case pending against the Nutrilite group and the dismissal of the criminal case, as well as some satisfactory termination of the ten libel actions pending in the District Court in San Francisco. It immediately became apparent that the area of discussion would be principally confined to the terms of the proposed consent decree.

Provisions of the Decree

The preamble recites that the decree is signed without any finding by the court on any issue of either fact or law.

Paragraph I adjudges that the court has jurisdiction of the subject matter and the parties.

Of the many items of printed material set forth in Paragraph II of the decree as being matter which cannot be used in connection with the sale of Nutrilite, all but two or three had previously been discontinued by Mytinger & Casselberry, Inc. Some argument ensued over the use of the reprint of the article entitled "Nutrition and Pregnancy," published in the *Ladies' Home Journal* of November, 1947, and the reprint of the article "We Feed Our Hogs Better Than Our Children," which appeared in *American Magazine* of October, 1947. It was the FDA's position that neither of these articles was supported by the consensus of scientific opinion and, although Nutrilite disagreed, the sales value of the reprints was so minor that it was agreed to discontinue their use. As indicated above, most of the other books and reprints had long previously been discontinued.

An interesting point of law was presented: Is literature which does not go to prospective customers but only to sales people "labeling" within the purview of the Act? It was FDA's position that instructions and educational material given to the distributors in the field do constitute labeling because the latter base their sales presentations upon the information that they gather from such material. Nutrilite contended that inasmuch as such materials were not intended for consumers' eyes and were not shown to the consumer, the latter could not be said to be influenced by such literature in deciding whether or not to buy. From the academic standpoint, the settlement of the litigation deprived the food and drug industry from securing judicial interpretation of this interesting question.

Paragraph II of the decree also prohibits the use of a film entitled "On the Other Side of the Fence" in its present form because the FDA contended that it inaccurately portrays the extent to which soil deficiencies contribute to vitamin-mineral deficiencies in man. The film is based upon the studies of one of the country's best-known authorities on soil deficiencies, but it was pointed out that there is a sharp difference of scientific opinion on this phase of nutrition. A number of other films used by sales people were not seriously objected to by the FDA and they were not listed as prohibited material.

Most of the prohibited claims listed in Paragraph III appeared to Nutrilite to be rather absurd. Nutrilite was assured, however, by the FDA that each of such representations had in fact been made by at least two Nutrilite distributors. Inasmuch as the Nutrilite group had insisted that the distributors sell the product only as a food supplement and not for any of the diseases mentioned, the prohibitions contained in Paragraph III with but two exceptions were not distasteful to the Nutrilite people. The two exceptions deal with arthritis and high blood pressure. Nutrilite contended that it had much evidence from customers (not from clinical tests) that the product had actually helped large numbers of persons who had or believed that they had had either arthritis or high blood pressure. FDA of course relies only upon clinical evidence.

As to the statements which are prohibited by the provisions of Paragraph IV of the decree, the principal controversy revolved around the necessity for including them within the prohibitions. It was explained by FDA that the statements had actually been made by some of the Nutrilite distributors. The reason for prohibiting the use of such statements is apparent from the mere reading of them.

Paragraph V is the one which has aroused much interest. Except for the findings of fact as to dietary food labeling, published in the *Federal Register*, November 22, 1941, this is the first time in the history of the Federal Food and Drug Administration that it has set forth in an official document claims as to efficacy which may be made in connection with the sale of a vitamin and mineral product. It is, therefore, Paragraph V of the decree which will probably receive the most careful study by industry in order that vitamin and mineral manufacturers may know what claims may be made with the approval of the FDA.

As may be expected, there was much wrangling over the wording of this paragraph. The FDA finally agreed that there are many

symptoms and conditions which can be caused by a lack of vitamins and minerals in the diet. Accordingly, the decree points out that many of the symptoms and conditions could be avoided if the diet contains a sufficient amount of the vitamins and minerals known to be needed in human nutrition and, further, that if the symptoms are the result of vitamin or mineral deficiencies they may be corrected by the use of appropriate vitamins and minerals (and, consequently, by Nutrilite Food Supplement) if taken in sufficient quantity and over a proper period of time.

Qualifications, such as the statement that many of the symptoms could be caused by other factors, are found in Paragraph V, which lists a large number of symptoms and physical conditions which may be, but are not necessarily, due to vitamin or mineral deficiencies.

A partial list of the symptoms and conditions which the consent decree states may be helped by Nutrilite Food Supplement follows. This is not a complete list, but is set forth merely to indicate the type of conditions which the FDA admits may be benefited by good vitamin and mineral supplementation, if the conditions have been caused by deficiencies: vague aches and pains; anemia; anemia, iron deficiency; tendency to bleed excessively from minor wounds; improper coagulation of blood; constipation; defective gums; defective teeth; diarrhea; digestive upsets; dizziness; dryness of hair or skin; fatigue; simple goitre; headache; insomnia; irritability; lack of energy; loss of appetite; loss of muscle tone; loss of weight; lowered resistance to infection of the mucous membranes of the eye or other organs; mental depression; nervousness; neuritis; nutritional night blindness; palpitation of the heart; poor bone and tooth development in the growing child; pyorrhea; rickets in infants; sores about the angles of the mouth; sponginess of the gums; weakness.

Paragraph VI offered no obstacle to the settlement. It merely sets forth in the decree the requirement of Section 502 (f), Regulation 1.106, of the Act that all the conditions for which the article is intended must appear somewhere in the labeling.

Paragraph VII sets forth prohibited acts while the article is held for sale after interstate shipment. It is divided into three categories:

(1) It prohibits the use of certain literature, none of which was ever shipped in interstate commerce by the Nutrilite people, but all of which the FDA stated had been used by some distributors. This prohibition was extended to any literature, unless expressly authorized in writing by Mytinger & Casselberry, Inc.

(2) The use of any literature which would violate any of the other provisions of the decree if shipped in interstate commerce.

(3) The representing that the product is useful in the prevention, treatment or cure of any condition that is not stated in the labeling.

Paragraph VIII was the subject of much debate. The FDA took the position that all testimonials should be prohibited without qualification. Nutrilite argued that testimonials are in the category of any other statements made in connection with sales presentations and that the legality and propriety of testimonials should be measured by the same standards as those used in measuring the legality of any other form of representation. Finally, Paragraph VIII was drawn so as to permit the use of testimonials—whether written, printed, graphic or oral—if the representations made thereby do not otherwise violate any other provision of the decree. It further states that testimonials shall be regarded as if the representations contained therein were made directly by the person using or causing the testimonial to be used.

Paragraph IX provides that Mytinger & Casselberry, Inc., must instruct all distributors to forward to it all literature which they had obtained from Mytinger & Casselberry, Inc., which may no longer be used under the terms of the settlement. It also provides that Mytinger & Casselberry, Inc., shall direct all distributors to use no written, printed or graphic matter without its written authorization.

Paragraph X provides that no person may be authorized to sell Nutrilite until he has been trained and until he has been approved by Mytinger & Casselberry, Inc.; that no persons may distribute the product until they have been instructed as to both the prohibited and the allowable claims (the FDA first insisted that a copy of the decree must be given to new distributors, but finally agreed that the same result would be reached insofar as public welfare is concerned if the newcomers were merely instructed as to what they could and could not say); and that no one may make any representation as to the qualifications and professional background of anyone associated with Mytinger & Casselberry, Inc., and Nutrilite Products, Inc., beyond those expressly authorized by those companies.

Paragraph XI provides that each person who was a distributor as of the date of the decree must sign a statement acknowledging that he has read the decree. Mytinger & Casselberry, Inc., not only welcomed this provision, but went beyond it and, upon its own voli-

tion required all of its distributors not only to read the decree, but to agree in writing to abide by the terms.

Paragraph XII was the subject of much controversy. FDA had always refused to review literature, taking the position that that was a matter for the courts to determine. However, the early drafts of the consent decree, which were presented by the FDA, provided that all literature used in the merchandising of Nutrilite *must* be first submitted to the FDA for approval before it could be used. Of course, this suggested provision met with immediate resistance. The paragraph in its final form gives to Nutrilite the right at its option to submit its literature to the FDA for inspection and comment. If the comment is not forthcoming within a reasonable time, Nutrilite may at its option go before the court and seek modification of the decree to authorize use of the literature. Application may be made to the court in the first instance without submission to the FDA or, if desired, the literature may be used without submission to either the FDA or the court. It was deemed advisable, however, to have the right to secure the comments of the FDA or to secure court approval whenever such approval seemed advisable.

Pursuant to Paragraph XIII, the criminal action was dismissed and it was also provided that the libel proceedings then pending in the northern district of California should be terminated pursuant to a stipulation which was attached to the decree. The terms of the stipulation regarding the disposition of the libel cases were the subject of considerable dispute. This was one of the problems which generated considerable heat. The FDA would not consent to dismissal of the ten cases, probably because its litigation record would suffer accordingly. On the other hand, Nutrilite was equally adamant in rejecting the demand that a judgment of condemnation in those cases be entered. It argued that the booklet *How to Get Well and Stay Well,* which constituted the alleged misbranding in the libel cases, had been already found not to be false or misleading in any particular by the only court which had ever passed upon any of the Nutrilite literature. That, of course, was the three-judge court sitting in Washington, D. C. A middle ground had to be found, and it was finally agreed that if the seized products could be given to third parties the court would thereby lose jurisdiction of the *res* and would accordingly lose jurisdiction of the cases themselves, and the litigation would die without any disposition having been made one way or the other. It was also agreed that inasmuch as the products had been seized in 1948, it was probable

that the potencies of the vitamins had diminished. Without making a complete assay of the potencies, Nutrilite could not afford to sell the material which had been held so long. If the potency of any of the vitamins had fallen below label claims, the product would be unsaleable. It was therefore agreed that the marshals of the districts in which the seized Nutrilite products were then located should deliver them to charitable institutions with an explanation that they may be below label potency. It was further agreed that the seized literature should be delivered to Mytinger & Casselberry, Inc., for disposition in accordance with the provisions of the decree, that is, that it should not be used in the sale of Nutrilite. Finally, it was provided that the cost bonds filed by the claimant in the various libel proceedings should be discharged, and the monies deposited as bonds should be returned to Mytinger & Casselberry, Inc., in full. Pursuant to this stipulation, orders were entered accordingly by the court in the northern district of California.

Paragraph XIV provides that nothing in the decree shall prevent the parties from doing any act authorized by the Federal Food, Drug, and Cosmetic Act or any other provision of the law.

Paragraph XV relieves Mytinger & Casselberry, Inc., and Nutrilite Products, Inc., of any liability for acts done or statements made by a distributor unless the act was done or statement made or caused to be done or made by an officer, employee or person acting under authority from those companies. Most of the discussion as to the content of this paragraph dealt with its wording rather than with its intent and purpose.

Paragraph XVI is short. It provides simply: "All claims for relief presented by the pleadings herein, which are not specifically granted by this decree, are hereby waived." Nevertheless, some time elapsed before agreement was reached on the wording. The paragraph was aimed primarily at that portion of the prayer of the complaint asking:

> That the defendants be required to tender to all purchasers of Nutrilite Food Supplement, past and present, a refund of all amounts collected by said defendants from said purchasers, as the sale price of said article.

The Nutrilite group had always considered this demand to be absurd and deserving of no serious thought. It was looked upon merely as a publicity stunt, which had in fact resulted in widespread publicity at the time the amended complaint, which included this

prayer for the first time, was filed. The original complaint had been filed shortly before the trial of the three-judge case in Washington, D. C., which had resulted in a unanimous decision absolving Mytinger & Casselberry's literature from any stigma, and excoriating the FDA officials for their unfairness in the manner in which they conducted their campaign against Nutrilite. The cases upon which the so-called "restitution" theory was based had been decided by the United States Supreme Court long before the original complaint was filed, but it was not until after the decision of the three-judge court that the amended complaint was filed, which included the demand for repayment of the purchase price. Nutrilite was also of the opinion that the FDA itself had no faith in the "refund" theory, for the new complaint did not even allege that any person had purchased the product in reliance upon any alleged misrepresentation, direct or implied. It was considered that the only purpose of the "restitution" prayer was to gain publicity damaging Nutrilite and to satisfy to some degree the chagrin of the FDA officials which the three-judge court decision had created. This view had, in the opinion of Nutrilite, been given credibility by the deposition of Paul B. Dunbar, taken on March 2, 1951, portions of which concerning the so-called "restitution" prayer are as follows:

Q. (By Mr. Rhyne) And you do not know of any provision of the Food Drug and Cosmetic Act which actually authorizes this relief?

A. There is none that I know of.

Q. You think it is a good policy for you to request such relief for the first time in a case which—strike that, Mr. Reporter. In this three-judge case to which I referred, are you familiar with the findings of fact of that court?

A. I read them.

Q. Have you ever referred to those findings of fact as stigmatizing the officials, like yourself, in the Food and Drug Administration?

A. Yes, I think I made a speech in which I referred to that. You probably heard it. In fact, I think you were sitting on a front seat grinning at me like a Cheshire cat. Do you want me to get the speech and read it into the record?

Q. Well, I do not believe we have quite the time for that now, but my main point was that you felt that those findings did stigmatize you personally.

A. Oh, yes. . . .

Q. Do you think that in view of the fact that these three impartial judges held that you were 100% wrong in making the conclusion that you did that this labeling was false and misleading, that it was fair to use this litigation as a test case in which to request refunds?

A. Well, you use the term "impartial judges." I sat through a great deal of that proceeding and, as a layman, my conviction was that they did not consider the evidence the government had to establish the falsity and the falsely misleading

character of these representations. It was our opinion that I don't know if their opinion carried very much weight or more weight on that subject than in the ordinary layman's view. We got the views of individuals in the Food and Drug Administration who have had long experience in the evaluation of labels; we have opinions reached by the Acting Administrator, Mr. Kingsley, entirely independently of our own; views reached by Mr. Crawford, Mr. Larrick and Mr. Murray, not to mention the indictment in the proposed criminal proceedings by a Grand Jury in San Francisco.[3] Somehow or other I feel that the weight of those opinions outweighs that of the three judges, and I say that with all respect to the court. . . .

Q. When you say Congress has appropriated money to carry out the Food and Drug Act, it does not appropriate money to enable those individuals within the Food and Drug Administration to clear yourselves of stigmatizing charges made by three judges, does it?

A. I don't think we have ever included in our appropriation estimates any specific sum for that purpose. In fact, I am certain that we have not. But we have invariably presented to Congress estimates, which include the preparation and presentation of evidence in court trials.

Accordingly, during the negotiations for settlement, the "restitution" prayer was the object of much bantering. It was never pressed but was quickly abandoned by the FDA.

Although the FDA surrendered the so-called "restitution" theory without a fight, it did urgently contend that the settlement decree should not be worded in such a manner that it could be construed as a judicial rejection of the "refund" theory. The early drafts of the decree submitted by Nutrilite provided that all claims for relief which were not granted by the decree should be denied. This would include not only the prayer of the complaint for so-called "restitution," but also the Nutrilite countercharges against the FDA officials of arbitrary, oppressive and unlawful conduct. The FDA objected to the use of the word "denied" on the ground that it would indicate an adjudication to the effect that the prayer for the so-called "refund" had no foundation in law. After lengthy discussion, it was agreed to substitute the word "waived" for "denied"; and so the "refund" theory remains alive in the FDA's arsenal of weapons—ready to be withdrawn at some future time when some other shipper incurs the wrath of the gods.

Paragraph XVII dismisses the action as to the individual defendants, leaving as the remaining defendants the corporations, Mytinger & Casselberry, Inc., and Nutrilite Products, Inc.

[3] Author's note: The indictment did not involve any editions of literature which were before the three-judge court. It involved the first edition which had been abandoned by Mytinger & Casselberry, Inc., approximately a year before the three-judge case was filed.

Paragraph XVIII is the usual provision for retention of jurisdiction in the court to enable any party to apply for such further orders and judgment as may be appropriate to interpret or carry out the judgment, to enforce compliance therewith, to punish violations thereof and to interpret its provisions. It also extends the right for any party to move for modification in the event of changed conditions of law, fact or scientific opinion. This was deemed necessary in view of the fact that the science of nutrition is still in its infancy and new facts concerning it are rapidly being developed.

The saving clauses are of particular interest. Paragraph V, which sets forth the allowable claims, includes the following subparagraph:

> That the specifications of the foregoing allowable claims shall not preclude the making of other claims or representations which conform to all the provisions of the Federal Food, Drug and Cosmetic Act including representations based upon generally accepted scientific facts in the field of nutrition; nor shall the foregoing specifications preclude the making of statements or representations which are supported by reliable scientific opinion, although not supported by the consensus of scientific opinion, provided the statements or representations are qualified by an explanation that a difference of reliable scientific opinion respecting the same does exist; and in the event of conflict between the provisions of this subparagraph 31 and any other provision of this decree the provisions of this subparagraph 31 shall prevail.

It is important to the entire industry because frequently, notwithstanding Regulation 1.3, the FDA will reject a claim of efficacy, even though it be supported by a considerable body of reliable scientific opinion, taking the position that statements of efficacy should not be made unless supported by the consensus or weight of such opinion. Because of the possibility that other provisions of the decree may be in conflict with this broad saving clause, it was provided that the latter shall prevail in the event of any such conflict being noted.

The second saving clause, Paragraph XIV, reads as follows:

> . . . and it is further
>
> ORDERED, ADJUDGED, AND DECREED that nothing in this decree shall be construed as to prevent defendants from doing anything which is authorized under or by the Federal Food, Drug and Cosmetic Act, as amended, or any other provision of law, nor shall this decree deprive said defendants of the immunities conferred by said Act as now in force or as hereafter amended, and in the event of conflict between this paragraph and any other provision of this decree, the provisions of this paragraph shall prevail.

Paragraph XVIII reads as follows:

> . . . and it is further
>
> ORDERED, ADJUDGED, AND DECREED that jurisdiction of this Court is retained for the purpose of enabling any of the parties to this judgment to apply

at any time for such further orders and directions as may be necessary or appropriate for the construction or carrying out of this judgment or for modification of any of the provisions thereof and for the purpose of enforcing compliance therewith and the punishment of violations thereof. Nothing herein shall prejudice the right of any party to move the Court for modification of this judgment in the event of changed conditions of law, fact, or scientific opinion.

These saving clauses were inserted only after prolonged discussion. The defendants, of course, rebelled at being bound by any inflexible provisions of the decree and it was finally agreed that the wording of the saving clauses would better meet the ends of justice.

The final draft was signed by the interested parties on April 5, 1951, and was immediately presented to the court. It was signed by the court the following day, April 6, 1951.

The prolonged negotiations ended in an atmosphere of friendliness and with mutual pledges of cooperation. The FDA promised that the prohibitory provisions of the decree would be enforced against all members of the industry, and Nutrilite, on its part, agreed that both sides should bury the hatchet "and not in each other's heads." So ended, at least for the time being, one of the most bitterly fought litigation wars in the history of the Federal Food, Drug, and Cosmetic Act. **[The End]**

• *Federal Security Agency Awards* •

Dr. Paul B. Dunbar, retired Commissioner of Food and Drugs, the Kansas City District, and eight employees with 40 or more years of federal service were honored by the Federal Security Agency in an awards ceremony held in the Federal Security Building auditorium on December 13. Federal Security Administrator Oscar R. Ewing, in presenting the awards, said: "These are the times when such recognition for the government worker is badly needed, for the government worker is being misrepresented to the public. He is being criticized. His quality and his integrity are under heavy attack." Mr. Ewing added that it is the scattered few who have transgressed and they should be exposed so that the probity of the overwhelming majority of loyal workers will not be subject to suspicion.

Dr. Dunbar received the Agency's highest award, a gold medal for distinguished service, given in recognition of his service in protecting the health and welfare of consumers through "outstanding leadership in the constructive administration of food and drug laws."

The Kansas City District was awarded a superior service citation for "exceptional service in the performance of duties under difficult conditions during the Kansas City flood of 1951."

Eight of the Agency's 30 length-of-service awards for 40 or more years of federal service were received by Food and Drug Administration employees.

Significant Comments

By EDWARD E. TURKEL,
Hearing Examiner,
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Judicial
Administrative
and Legislative

Acquittal in Prior Criminal Action Does Not Bar Seizure of Same Product

Two decisions have been handed down which sustain the view that a seizure action can be maintained against an article alleged to be violative of the Federal Food, Drug, and Cosmetic Act even though the claimant was acquitted in a prior criminal case charging interstate shipment of the same product in violation of the Act.

In one of the seizure actions, the government sought to condemn shipments of an edible blend of vegetable oils, charging adulteration and misbranding. The criminal action charging shipment of such goods was terminated by the entry of a judgment of acquittal. The claimant, who was a defendant in the criminal action, applied for a summary judgment in the seizure actions, contending that the judgment of acquittal is conclusive in his favor as regards the seizure proceedings in that the goods, issues and parties are identical in both criminal and seizure actions. Although the government contended that additional violations were involved in the seizure actions, and hence the issues were not entirely the same, the court said that it did not think it necessary to decide the identity of issues.

In denying the claimant's motion, the court relied upon decisions cited in the opinion, and held that the acquittal does not bar seizure proceedings under the Federal Food, Drug, and Cosmetic Act since such proceedings are purely civil and remedial in nature, in that the object is to quarantine a prescribed article in order to prevent injury to the public health or deception to the public. The court distinguished such statutory design from the provisions of other statutes, the object

The Author Discusses Some Current Legal Developments in the Food, Drug and Cosmetic Fields. Among the Products Involved in the Cases Analyzed Are Books, Orange Drink, Tomatoes and Phonograph Records

of which is to punish violators of law, such as provisions for forfeiture of vehicles used in the commission of an offense resulting in confiscation of the vehicle. The court went on to say that it is only in such latter instance that an acquittal in a criminal action bars proceedings for the forfeiture of property. (*U. S.* v. *38 Cases, etc. Figlia Mia Brand*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7211 (DC N. Y., August 8, 1951).) The court seems to be of the opinion that the doctrine of *res judicata* does not apply in view of the difference in degree of burden of proof in civil (i.e., seizure) and criminal cases. Generally speaking, the doctrine of *res judicata* operates to bar an action involving the same issues as litigated in a prior suit between the same parties or their privies. The degree of burden of proof in a criminal action is, of course, greater than in a civil action, that is, proof beyond a reasonable doubt as contrasted to proof by the preponderance of the evidence in a civil action.

In the other seizure case referred to above, the court of appeals reversed the action of the district court granting a summary judgment to the claimant on the ground that the issues in the seizure action had been adjudicated in the claimant's favor in the prior criminal case, contrary to the result reached in the *Figlia Mia* case (*U. S. v. Walter W. Gramer, Claimant, etc.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7217 (CA-9, September 28, 1951)).

In the *Gramer* case, the seizure and prior criminal actions involved the same drug preparation, labeling and material issues, but the seizure action was brought to condemn a different shipment of the same drug. In holding that the seizure action was not barred by the prior acquittal in the criminal action, the Court of Appeals considered the applicability of the doctrine of *res judicata* and the constitutional guaranty against double jeopardy (that is, guaranty from a second prosecution on the

merits for the same offense). Relying upon decisions of the United States Supreme Court, the court of appeals held that the doctrine of *res judicata* is precluded because of the difference in degree of burden of proof in criminal and civil cases, and that the constitutional guaranty against double jeopardy is inapplicable since the seizure action did not seek to condemn the same shipment of drug involved in the criminal action and for the further reason (as held in the *Figlia Mia* case) that seizure proceedings under the Federal Food, Drug, and Cosmetic Act are not punitive in character—the object being not to punish the owner of the goods, but to protect the public.

The court reasons that if acquittal in the prior criminal case can be said to control the disposition of the question, an acquittal, even through wholly inadequate proof of violation of the Federal Food, Drug, and Cosmetic Act, could practically stop the government from preventing the sale of a most harmful or wholly ineffective nostrum, a result that would not be justified unless clearly required. This decision is significant, since it is the first known expression of an appellate court concerning the effect of a prior acquittal upon seizure proceedings against the same product under the Federal Food, Drug, and Cosmetic Act.

Additional Samples Denied; Depositions Authorized Under Act

In the *Figlia Mia* case, discussed above, the court also passed upon two other matters presented to it. First, the government applied for an order allowing it to sample the articles to determine if they are presently merchantable as food. This application was contested by the claimant upon the ground that the government had samples of the merchandise and such samples were used at the previous criminal trials. The government countered that such samples were obtained by purchase before the criminal and seizure proceedings were instituted. The court denied the government's application. The court said that there was no satisfactory explanation by the government with respect to the claimant's contention, and it did not appear there was a need for additional samples. The court further held that the present condition of the seized articles is immaterial, the test being whether the articles were adulterated when shipped and while in interstate commerce, and that the samples previously obtained should be sufficient to enable the government to meet its burden of proof as to that issue in the present proceeding.

Second, the court denied the claimant's action to vacate the notice by the government to take claimant's deposition. The claimant contended that since seizure proceedings under the Federal Food, Drug, and Cosmetic Act are required to conform as nearly as may be to seizure in admiralty and because admiralty proceedings do not allow for such depositions, no authority exists. In rejecting such contention, the court follows the teachings of other decisions cited in the opinion, namely, that it is now well established that the rules of civil procedure, which permit such depositions, apply to condemnation proceedings.

Books Held to Be Labeling

As reported in the June, 1951 issue of the FOOD DRUG COSMETIC LAW JOURNAL, the government brought a seizure action against a quantity of blackstrap molasses and a number of books entitled *Look Younger, Live Longer,* by Gayelord Hauser, and upon motion of the publisher the libel was dismissed against the books, the court holding that the allegations in the libel failed to show that the books have a relation to the molasses so as to constitute the books labeling for the food. (The government charged that the books, as labeling, misbranded the molasses because statements in the book concerning the benefits to be derived from the use of the molasses were false and misleading.)

After the libel was dismissed the government filed an amended libel charging that the book accompanied the molasses as labeling when the article was introduced into, while in, and while held for sale after shipment in interstate commerce in that the books and molasses were shipped interstate via the same carrier, had a common origin and destination, and were displayed together in the retail food store where the molasses and books were seized, and that the books were otherwise used in the retail store to promote the sale of the molasses, thus showing the connection of the books and the food in the distributional scheme of marketing the molasses. The publisher of the books moved to dismiss the amended libel against the books. The court denied the motion. The court said that the publisher concededly was not a party to the plan of distribution and had no connection with the dealers of the molasses. The court, however, rejected the publisher's contention that the Federal Food, Drug, and Cosmetic Act does not authorize seizure of books as "labeling," and that seizure construing the books as "labeling" would violate the constitutional guaranty of freedom of the press. The court said that resort to the

seizure provisions of the Act does not undertake to interfere with the publication or circulation of the books, inasmuch as the seizure does not relate to the books offered for bona fide sale, but only to copies claimed to be offending against the Act by being associated with the molasses in a distributional plan in such manner as to misbrand the product. A default decree of condemnation has since been entered. (*U. S. v. 8 Cartons etc. "Plantation . . . Blackstrap Molasses, etc., including 25 Copies, etc. "Look Younger, Live Longer" by Gayelord Hauser, etc.,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7210 (DC N. Y., August 2, 1951).)

The basis of the court's refusal to dismiss the amended libel are the allegations therein contained to the effect that the books and molasses were parts of an integrated distribution program, following the teaching of the *Kordel* case (*Kordel v. U. S.*, 335 U. S. 345, 350).

Promulgations

A final order has been promulgated establishing definitions and standards of identity for canned corn and canned field corn, establishing a standard of quality for canned corn and establishing standards of fill of container for canned corn and canned field corn (CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 2503-2506, 16 F. R. 7644, August 4, 1951). These regulations, which became effective January 1, 1952, follow the publication of the tentative order reported in the October, 1951 issue of FOOD DRUG COSMETIC LAW JOURNAL. No exceptions were filed to the tentative order.

A final order has been promulgated amending the definition and standard of identity for evaporated milk (CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 2215, 16 F. R. 7819, and following, August 9, 1951). The amendments to the definition and standard (CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 2215, 21 CFR Sec. 18.520) do the following: increase the total vitamin D content from 7.5 units per fluid ounce, minimum, to 25 U. S. P. units, minimum (paragraph (a) (2)), and set forth a new method for determination of quantity of vitamin D, to wit, the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists" (regulation paragraph (a)(5)).

There were also promulgated orders amending the regulations for tests and methods of assay for antibiotic and antibiotic-containing drugs (21 CFR 141.1, and following, and 1950 Supplement) and for

certification of batches of such drugs (21 CFR 146.1, and following, and 1950 Supplement) with respect to the following: chloramphenicol palmitate (Sections 141.305, and following, and 146.306, CCH Food Drug Cosmetic Law Reports ¶ 1625, 16 F. R. 7983, and following); aureomycin gauze packing and aureomycin dressing (Sections 141.213, and following, and 146.213, and following, CCH Food Drug Cosmetic Law Reports ¶ 1612, 16 F. R. 8236, and following). These orders became effective on date of publication in the *Federal Register*, namely, August 14, and August 18, 1951, respectively. In addition, there were promulgated the following amendments to the regulations relating to antibiotic and antibiotic-containing drugs: Section 146.45, changing the labeling declarations as to expiration date of procain penicillin in oil; Section 146.51, providing new requirements for labeling and expiration dates of certain penicillin drugs and setting forth new requirements relating to certification of such drugs (CCH Food Drug Cosmetic Law Reports ¶ 1524, 1530, 16 F. R. 8221, and following). These amendments became effective on date of publication in the *Federal Register*, August 31, 1951.

The Federal Security Administrator promulgated a statement of general policy or interpretation in the form of a notice to manufacturers and labelers of antibiotic drugs for veterinary use cautioning that unless a proper interval of time is allowed following the use of antibiotic drugs for the treatment of mastitis in milk-producing animals, the drugs may get into the general milk supply; and that milk, containing antibiotic drugs, to be sold for human consumption or for manufacturing into cheese may be considered adulterated. The notice also cautions that antibiotic drugs intended for intramammary use in the treatment of mastitis in milk-producing animals should bear suitable warnings (CCH Food Drug Cosmetic Law Reports ¶ 7212, 16 F. R. 8270, August 21, 1951).

A notice of proposed rule-making has been promulgated which proposes to amend the definition and standard of identity for canned tomatoes (CCH Food Drug Cosmetic Law Reports ¶ 2119, 21 CFR 53.40), by deleting the following requirement in Paragraph (b): that the label bear the statement "with added strained tomatoes" when the liquid strained from mature tomatoes is used as an optional ingredient to fill the spaces between the tomato fruits in the container (CCH Food Drug Cosmetic Law Reports ¶ 2119, 16 F. R. 9699, September 22, 1951). The present regulation does not require a pertinent label dec-

laration when use is made of liquid draining from tomatoes during and after peeling and coring as an optional ingredient to fill the spaces. The proposal, therefore, is to eliminate, insofar as label declarations are concerned, the distinction between these optional ingredients used for the purposes above mentioned. The notice provides that interested persons whose appearances were filed at the hearing may file exceptions within 30 days from the date of publication of the notice, which exceptions may be accompanied by supporting briefs.

Orange Drink Not Adulterated

The United States Supreme Court has denied the government's petition for a writ of certiorari to review the decision of the United States Court of Appeals for the Third Circuit vacating the decree and remanding the case to the United States District Court for the District of New Jersey. (*U. S. v. 88 Cases, etc. "Bireley's Orange Beverage,"* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7199 (CA-3, March 23, 1951). The opinion of the court of appeals was discussed in the June, 1951 FOOD DRUG COSMETIC LAW JOURNAL, at page 464.

Transfer of Seizure Action

The United States Supreme Court has denied the claimant's petition for a writ of certiorari to review the decision of the United States Court of Appeals for the Fourth Circuit refusing the claimant's motion to transfer the seizure action to another federal judicial district from the district where the goods were found and the action instituted. (*Clinton Foods, Inc. v. U. S., etc.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7200 (CA-4, April 2, 1951). The opinion of the court of appeals was discussed in the June, 1951 FOOD DRUG COSMETIC LAW JOURNAL, at pages 469-470.

Proof of Adulteration of Food Products

The government brought four seizure cases, each case involving a separate shipment, against articles of food alleged to be adulterated in that the articles contained decomposed tomato material, and were, further, prepared under insanitary conditions whereby they may have become contaminated with filth. It was also charged that two of the articles were further adulterated in that they contained fly maggots.

All four cases were consolidated for trial, and the trial resulted in the government's favor. (*U. S. v. 44 cases, more or less of an article labeled in part "Viviano Spaghetti With Cheese," et al.* (DC Ill., November 12, 1951).)

The memorandum opinion discusses matters relating to the evidence presented at the trial. With respect to the charged insanitary conditions, the first inspection of the plant took place about one month after the first shipment. Other inspections took place a few days after the rest of the shipments were made. The government witnesses testified that the plant and equipment were unclean, and the plant infested with flies at the times of the inspections. The claimant's witnesses, on the other hand, testified to more favorable conditions at the plant than were disclosed by the government's witnesses, and produce men supported the claimant's testimony that he bought good tomatoes. The court found, upon all the evidence, that insanitary conditions existed at the plant at the times the inspections were made. It said that the insanitary conditions resulted in most part from conditions of a continuing nature, such as lack of screens, flies, dirt on walls and floors, etc. compelling the inference that insanitation existed when the seized articles had been prepared and packaged at the plant. The claimant introduced evidence intended to refute the testimony of the government's witnesses that the articles contained decomposed tomato material and insect filth, but the court gave greater weight to the testimony of the government's witnesses based upon its determination that claimant's expert lacked experience in the field of decomposed substances in food and particularly in the field of tomatoes and tomato molds. The court also said that the testimony of the government's witnesses was strengthened by proof of insanitary conditions at the plant, since it could be expected that such filth would become incorporated in the products prepared at the plant. The court overruled claimant's objection to the admissibility of enlargements of photographs to show the factory conditions, offered by the government, holding that claimant's objections that the enlargements exaggerated the conditions went to the weight to be given to them. The court followed the holdings of other cases cited in the opinion that an article of food is adulterated within the pertinent provisions of the Federal Food, Drug, and Cosmetic Act if it consists in whole or in part of a filthy, putrid or decomposed substance, irrespective of whether it is fit for food or injurious to health.

Phonograph Records Held to Be a Misbranded Device

As was reported in the June, 1950 issue of the FOOD DRUG COSMETIC LAW JOURNAL (pages 361-362), the district court dismissed a seizure action brought by the government against certain phonograph records alleging that such article is a "device" within the meaning of the Federal Food, Drug, and Cosmetic Act, in that it was intended to affect the function of the body—namely, induce sleep—and misbranded in that the claims made for the article in its labeling concerning its efficacy to induce sleep were false and misleading. The district court, in dismissing the libel, ruled against the government as concerned each of the allegations. The government appealed, and the judgment has been reversed. (*U. S. v. 23 More or Less Articles, etc.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7220 (CA-2, November 7, 1951).) The appellate court held that the article falls within the statutory definition of "device" upon the reasoning that the article is at least a "contrivance" (one of the terms used in the definition) intended to induce sleep and that, according to the testimony of the expert witnesses, sleep is a function of the body, or body and mind. As to the charge of misbranding, the court held that the claims made for the article in its labeling give the impression that the article is a cure-all for insomnia from whatever cause or at least an adequate substitute for medication, while the evidence showed that such claims were extravagant. It concluded, therefore, that the article was misbranded within the meaning of the pertinent provisions of the Act which defines a drug or device as misbranded if its labeling is false or misleading in any particular.

Amendments to Antibiotic Drugs Regulations

The following orders have been promulgated amending the regulations relative to tests and methods of assay and certification of batches of antibiotic and antibiotic containing drugs 21 CFR (1950 Supplement) 141, 146):

Order providing for two new antibiotic preparations, namely, aureomycin therapeutic formula for animal feed; and aureomycin and vitamin B 12 formula for animal feed; for bacitracin ophthalmic solution and bacitracin with vasoconstrictor to be stored for seven days at room temperature. This order became effective November 8, 1951 (16 F. R. 11337).

Order providing for two new antibiotic preparations, namely, dibenzylethylenediamine dipenicillin G; and dibenzylethylenediamine

dipenicillin G oral suspension. This order became effective November 22, 1951 (16 F. R. 11807).

Correction to regulation pertaining to certification of batches of penicillin tablets and aureomycin with vasoconstrictor (*Federal Register,* October 25, 1951, page 10847) as follows: insert "finders, lubricants" between "diluents" and "colorings" in Section 146.27 (a) (CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 1497, 16 F. R. 11910).

Exemptions for Retail-Packaged Foods

A notice of proposed rule making was issued to provide for labeling exemptions for foods packaged in retail food establishments. It is proposed, under stated conditions, to exempt such repackaged foods while held for sale after shipment in interstate commerce from the following sections of the Federal Food, Drug, and Cosmetic Act: 403 (e)(2), requiring label statement of quantity of contents; 403 (i)(2), requiring label declaration of ingredients; 403 (k), requiring label statement of artificial flavoring, artificial coloring and chemical preservatives. The notice also informs of proposed administrative intention to refrain from recommending regulatory action where such repackaged foods do not comply with the following sections: 403 (e)(1), requiring label statement of name and place of business of manufacturer, packer, or distributor; 403 (g)(2), requiring label designation of identity-standardized food and common name of optional ingredients, subject to stated conditions; 403 (i)(1) requiring label statement of common or usual name of the food, subject to stated conditions (16 F. R. 11458).

New Seafood Inspection Regulations

Regulations have been issued providing for inspection of production of fresh-iced and frozen shrimp and specialty shrimp products at the option of the packer. Under the regulations, the Food and Drug Administration can now furnish continuous inspection of the packing of these products on application of producers who meet the requirements of the regulations. The inspection service is purely voluntary and is paid for by firms who take it. The regulations set forth standards for factories, equipment, raw materials and operating conditions. Firms which use the inspection service are entitled to state on the label that their shrimp has been prepared under government supervision. (16 F. R. 11072.) **[The End]**

REPORTS TO THE READER—Continued from page 4

Section on Food, Drug and Cosmetic Law in the New York State Bar Association, dealing with retail food exemptions from the Federal Food, Drug, and Cosmetic Act and published in the November issue of the FOOD DRUG COSMETIC LAW JOURNAL. (2) The Executive Committee of the Division had a dinner meeting on September 18, at the University Club in New York City. It discussed numerous food and drug law matters and informally reached conclusions with respect to some. Such informal conclusions were simply reported at this meeting of the Division, which took no action on them; and consequently they were not formally approved by the Division. They were: (*a*) disapproval of a transfer of the food administration of the Federal Food, Drug, and Cosmetic Act to the United States Department of Agriculture; (*b*) approval of elevating the United States Commissioner of Food and Drugs to the highest civil service classification, with a then due reclassification of his official associates in that service; (*c*) approval of the substitution of an objective definition of prescription drugs for an administrative one, in a prescription drug amendment to the Federal Food, Drug, and Cosmetic Act. No attorney of the Federal Government joined in these informal conclusions; and they have no force other than a non-official expression of opinion by the attending members of the Executive Committee. (*3*) The Chairman and Secretary of the Section were reelected. (*4*) The fourth annual meeting of the Division will be held at San Francisco, during the week of September 15 in 1952, when the American Bar Association will next convene, there.—Charles Wesley Dunn, Chairman; James M. Best, Secretary.

Dated: December 17, 1951.

Annex—Report of the Committee on Food Standards of the Food, Drug and Cosmetic Law Division of the Corporation, Banking and Business Law Section.—Your committee has given further study to the various recommendations that the prescribed procedure followed at and after the public hearing on any proposed food standard ought to be modified.

The committee has concluded to recommend that the Food, Drug and Cosmetic Law Division, through the appropriate channels, initiate and endorse the following proposals:

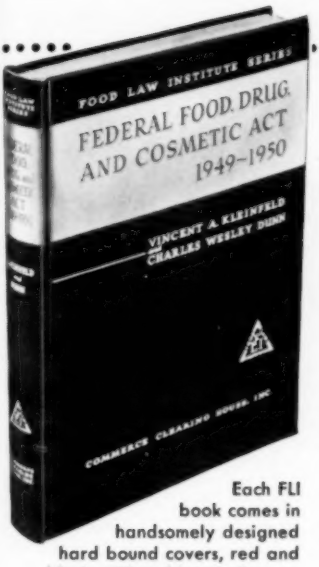
1. That the Act be amended to provide that where the promulgation of a food standard, or of any amendment to a food standard, does not involve any controversial issue, the Administrator be authorized initially to give public notice of the proposal and an opportunity for interested persons to present their views orally or in writing, with further provision that within a specified period any interested person may request and obtain a public hearing on any controverted issue, and absent any such request the standard may be issued without hearing.

2. That a request for hearing on a controverted issue may be made by any interested person without showing that the applicant represents the whole or any substantial portion of an interested industry.

3. That as to any controverted issue, the regulation ultimately issued must be predicated upon findings based in turn upon substantial evidence of record.

4. That the Federal Security Administration be requested to complete its work on the proposed revisions of the Rules governing the procedure at these hearings, and that a revision incorporating the desired changes, already proposed by the committee and others, be issued as soon as possible.

Respectfully submitted, H. Thomas Austern, Chairman; James M. Best; Franklin M. Depew; Paul M. Duff; George Faunce, Jr.; George S. Herr; Michael S. Markel; Samuel A. McCain.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